[Volume VI, Appx11515 – Appx20131]

Nos. 22-2069, -2070, -2071, -2072

IN THE

United States Court of Appeals

FOR THE FEDERAL CIRCUIT

MASIMO CORPORATION,

Appellant,

v.

APPLE INC.,

Appellee.

APPEAL FROM THE PATENT TRIAL AND APPEAL BOARD
CASE NOS. IPR2021-00193, IPR2021-00195, IPR2021-00208, IPR2021-00209

JOINT APPENDIX

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May 10, 2023

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Date	Paper No. /Ex. No.	Document	Pages
		Remote Physiological Monitoring [IPR2021-00193]	
	Ex. 1023	U.S. Pat. App. Pub. No. 2007/0145255 (Nishikawa) [IPR2021-00193]	Appx02598-02605
	Ex. 1025	U.S. Patent No. 6,801,799 (Mendelson) [IPR2021-00193]	Appx02610-2625
	Ex. 1047	Second Declaration of Thomas Kenny [IPR2021-00193]	Appx03558; Appx03560; Appx03562-3586
	Ex. 2004	Declaration of Vijay K. Madisetti, Ph.D. [IPR2021-00193]	Appx04781; Appx04811-4814; Appx04817-4823; Appx04829-4830; Appx04835-4839; Appx04843
	Ex. 2006	4/22/2021 Deposition Transcript of Dr. Thomas W. Kenny [IPR2021-00193]	Appx04884; Appx04934-4935; Appx04957-4960; Appx04966-4967; Appx04969-4973; Appx04976-4977; Appx04980; Appx04983-4984; Appx05015-5017; Appx05024-5026; Appx05037; Appx05047; Appx05062-5064; Appx05071-5073; Appx05081; Appx05085-5091; Appx05140
	Ex. 2007	4/23/2021 Deposition Transcript of Thomas W. Kenny [IPR2021-00193]	Appx05156; Appx05193-5194; Appx05214-5218;

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			Appx05224-5225; Appx05285; Appx05288
	Ex. 2008	4/24/2021 Deposition Transcript of Thomas W. Kenny [IPR2021-00193]	Appx05336; Appx05491-05492
	Ex. 2009	4/25/2021 Deposition Transcript of Thomas W. Kenny [IPR2021-00193]	Appx05602; Appx05682-05687
	Ex. 2027	9/18/2021 Deposition Transcript of Thomas W. Kenny [IPR2021-00193]	Appx06194; Appx06212-6215; Appx06242-6243; Appx06250; Appx06397-6398; Appx06406-6408; Appx06411-6412
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	Ex. 1003	Declaration of Dr. Thomas W. Kenny [IPR2021-00195]	Appx07469; Appx07512-7520; Appx07532-7534; Appx07545-7547; Appx07570-7577
	Ex. 1047	Second Declaration of Thomas Kenny [IPR2021-00195]	Appx08873; Appx08877-08900
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		Madisetti, Ph.D. [IPR2021-00195]	Appx10127-10130; Appx10133-10141; Appx10147-10148; Appx10160-10161
	Ex. 2006	4/22/2021 Deposition Transcript of Dr. Thomas W. Kenny in IPR2020-01520 [IPR2021-00195]	Appx10205; Appx10401-10402; Appx10408; Appx10410
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	Ex. 2027	9/18/2021 Deposition Transcript of Dr. Thomas W. Kenny [IPR2021-00195]	Appx11515; Appx11533-11534
11/20/2020	2	Petition for *Inter Partes* Review of U.S. Patent No. 10,258,266 [IPR2021-00208]	Appx11778; Appx11796; Appx11815; Appx11825-11827; Appx11830-11831; Appx11836
3/8/2021	6	Apple Updated Exhibit List - [IPR2021-00208]	Appx11866-11868
7/27/2022	33	Masimo Notice of Appeal to the U.S. Court of Appeals for the Federal Circuit [IPR2021-00208]	Appx12237-12239
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	Ex. 1047	Second Declaration of Thomas Kenny [IPR2021-00208]	Appx13759; Appx13763-13789
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		Madisetti, Ph.D. [IPR2021-00208]	Appx15012-15015; Appx15018-15026; Appx15032-15033; Appx15036-15037; Appx15039-15040; Appx15050-15051
11/20/2020	2	Petition for *Inter Partes* Review of U.S. Patent No. 10,376,191 [IPR2021-00209]	Appx16924; Appx16960; Appx16970-16972
3/8/2021	5	Apple's Updated Exhibit List [IPR2021-00209]	Appx17009-17011
7/27/2022	33	Masimo Notice of Appeal to the U.S. Court of Appeals for the Federal Circuit [IPR2021-00209]	Appx17359-17361
	Ex. 1002	Excerpts from the Prosecution History of U.S. Patent No. 10,376,191 [IPR2021-00209]	Appx17440; Appx17697-17699
	Ex. 1003	Declaration of Dr. Thomas W. Kenny [IPR2021-00209]	Appx17766; Appx17799-17816; Appx17822-17823; Appx17834-17845
	Ex. 1047	Second Declaration of Thomas W. Kenny [IPR2021-00209]	Appx18828; Appx18832-18858
	Ex. 2004	Declaration of Vijay K. Madisetti, Ph.D. [IPR2021-00209]	Appx20054; Appx20081-20084; Appx20087-20095; Appx20101-20102; Appx20105-20106; Appx20108-20110; Appx20120

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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APPLE, INC.,	Case IPR2020-01520
	U.S. Patent 10,258,265
Petitioner,	
	Case IPR2020-01539
	U.S. Patent 10,588,554
-against-	Case IPR2020-01537
	U.S. Patent 10,588,553
MASIMO CORPORATION,	Case IPR2020-01536
	U.S. Patent 10,588,553
Patent Owner.	
	Case IPR2020-01538
	U.S. Patent 10,588,554

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VIDEO-RECORDED DEPOSITION OF

THOMAS WILLIAM KENNY JR., PH.D.

Zoom Recorded Videoconference

09/18/2021

9:03 a.m. Pacific Daylight Time

REPORTED BY: AMANDA GORRONO, CLR

CLR NO. 052005-01

DIGITAL EVIDENCE GROUP

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Masimo Ex. 2027
Apple v. Masimo
IPR2021-00195

correct?

A. That's correct.

Q. The indication in this figure, "Toward the center," does that indicate the redirection that leads to the detector capturing light that otherwise would have been missed --

MR. SMITH: Objection; form.

Q. -- for a particular ray?

MR. SMITH: Same objection.

A. So just again, reading from Paragraph 42, the "lens' ability to direct light 'toward the center' would allow the detector to capture light that would otherwise have been missed by the detectors, regardless of their location within the sensor device."

Q. So there, there is some light that would have been captured by the detectors that is redirected and no longer hits the detectors; is that correct?

MR. SMITH: Objection; form.

A. So of all of the photons scattered backwards from all of these sites --

Q. Correct.

A. -- and interacting with this curved optical surface that we're calling the lens, some of those rays are diff- -- sorry -- refracted in a way that directs them toward the detectors which otherwise might have missed, and there would be some other rays that would have hit the detectors that are refracted away from the detectors; that's correct.

Q. So in your analysis, did you determine the relative amount of light that is refracted towards the detectors that would otherwise have been missed and compare it to the amount of light originally going to the detector that is now refracted away and misses the detector, with the presence of the convex surface?

MR. SMITH: Objection; form.

A. In order to perform such an analysis, I would need to know a full set of detailed dimensions and shapes of the objects that would be involved in that final design. So there was no such detailed calculation presented for this cartoon representation of the combination of elements from

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent of:	Poeze, et al.	
U.S. Patent No.:	10,258,266	Attorney Docket No.: 50095-0007IP1
Issue Date:	April 16, 2019	
Appl. Serial No.:	16/212,537	
Filing Date:	December 6, 2018	
Title:	MULTI-STREAM DATA COLLECTION SYSTEM FOR NONINVASIVE MEASUREMENT OF BLOOD CONSTITUENTS	

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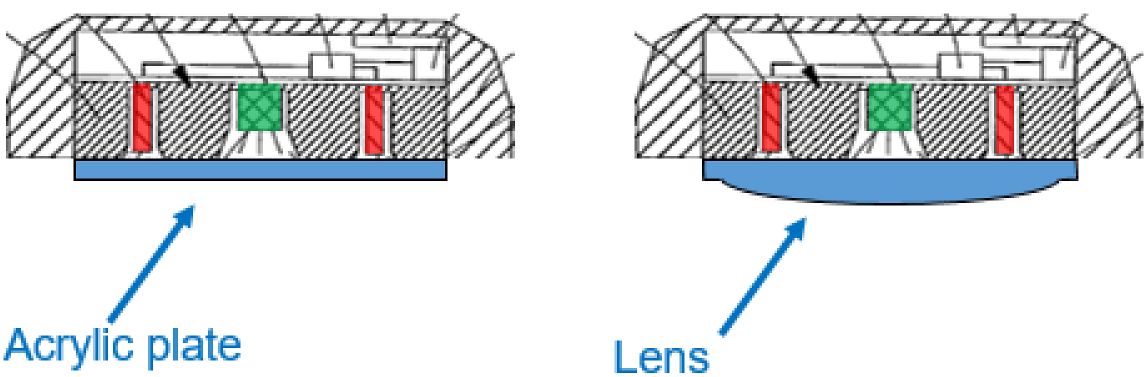
Patent Trial and Appeal Board
U.S. Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

PETITION FOR *INTER PARTES* REVIEW OF UNITED STATES PATENT NO. 10,258,266 PURSUANT TO 35 U.S.C. §§ 311–319, 37 C.F.R. § 42

1008, [0015]. Thus, a POSITA would have sought to incorporate an Inokawa-like lens into the cover of Aizawa to increase the light collection efficiency, which would lead to more reliable pulse detection. APPLE-1003, ¶¶88-89. The lens of Inokawa would provide precisely such a benefit to Aizawa's device by refracting/concentrating the incoming light signals reflected by the blood. *Id.*

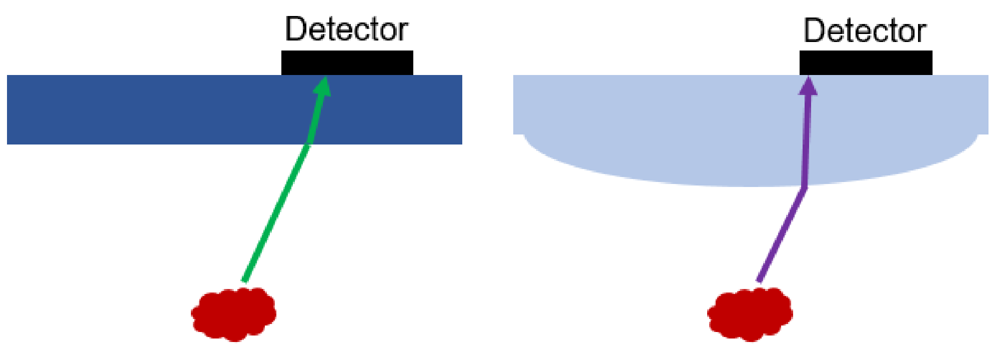
As illustrated below, the device resulting from the obvious combination of Aizawa and Inokawa would have modified the flat cover (left) such that it includes a lens as described in Inokawa (right) to "increase the light-gathering ability." APPLE-1008, [0015]; APPLE-1003, ¶89.



APPLE-1006, FIG. 1(b); APPLE-1003, ¶89.

A POSITA would have understood how to implement Inokawa's lensin Aizawa's device with a reasonable expectation of success, stemming from the signifi-

which is used to modify Aizawa as explained in Section III.A.3(a), serves a condensing function and thus, as with any other lens, refracts light passing through it. APPLE-1008, [0015], [0058]; APPLE-1003, ¶101. Thus, referring to the drawing below which compares the length of non-refracted light (*i.e.*, without a lens, left) bouncing off an artery with that of refracted light (*i.e.*, with a lens, right), it can be seen that the mean path length of light traveling to the at least four detectors is reduced—that is, the purple line is shorter than the green line. APPLE-1003, ¶102. This holds true for both the total length travelled as well as length travelled/attenuated through skin. *Id.*



APPLE-1003, ¶102.

Superimposing the two drawings above clearly shows the shortened path traveled by refracted light in the presence of a lens, both within the tissue as well as for total path length:

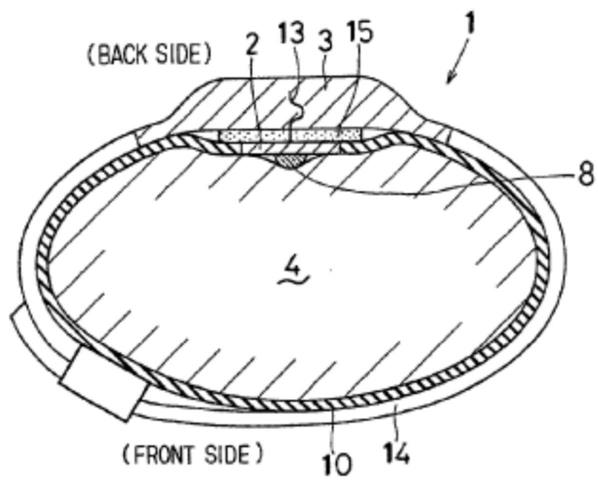
1006, FIG. 1(b); APPLE-1008, [0015], [0058]; APPLE-1003, ¶124. Moreover, because the lens acts as a light concentrator that improves the light-gathering ability of the modified device, the window would further provide a light concentrating function. *Id.*

B. [GROUND 1B] – Claims 1-6, 8-16, 18, and 19 are rendered obvious by Aizawa in view of Inokawa and Ohsaki

1. Overview of Ohsaki

Ohsaki is generally directed to "[a] pulse wave sensor includes a detecting element and a sensor body" where "[t]he pulse wave sensor is worn on the back side of a user's wrist." APPLE-1014, Abstract. As seen below, the pulse sensor of Ohsaki is "worn on the back side of the user's wrist 4...in the similar manner as a wristwatch is normally worn," *Id.*, [0016]; APPLE-1003, ¶¶63-64.

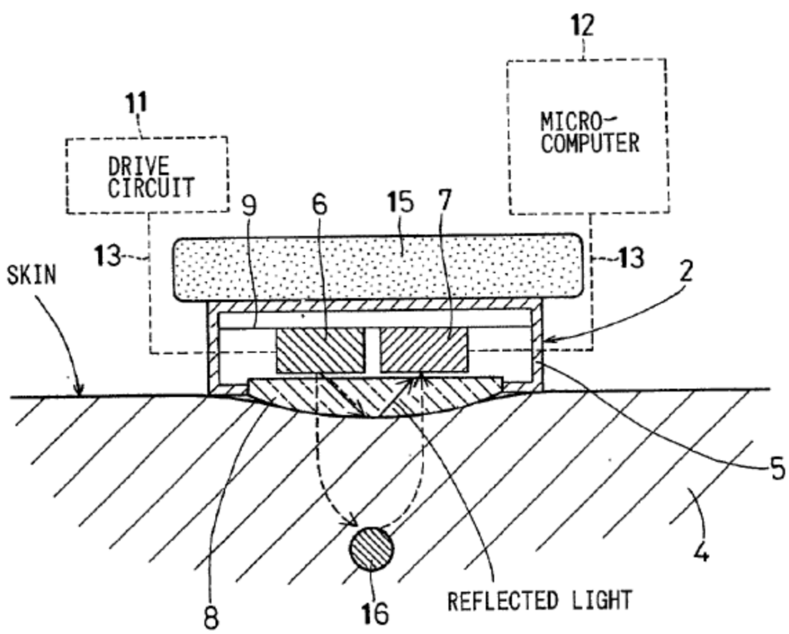
FIG. 1



APPLE-1014, FIG. 1.

Referring to FIG. 2 below, Ohsaki can sense pulse by emitting light through a light emitting element 6 and detecting reflected light using a light receiving element 7. APPLE-1014, [0017]. Ohsaki also provides a translucent board 8 that is transparent to light and includes a convex surface "in intimate contact with the surface of the user's skin." *Id.*, [0009], [0017].

FIG. 2



APPLE-1014, FIG. 2; APPLE-1003, ¶¶125-127.

2. Analysis

As described above in Ground 1A and Section III.A.3(a), a POSITA would have sought to incorporate an Inokawa-like lens into the cover of Aizawa to in-

crease the light collection efficiency. Here, Ohsaki provides an additional motivation and rationale for a POSITA to modify Aizawa to include a "lens" as per element [1d]. APPLE-1003, ¶¶128-129.

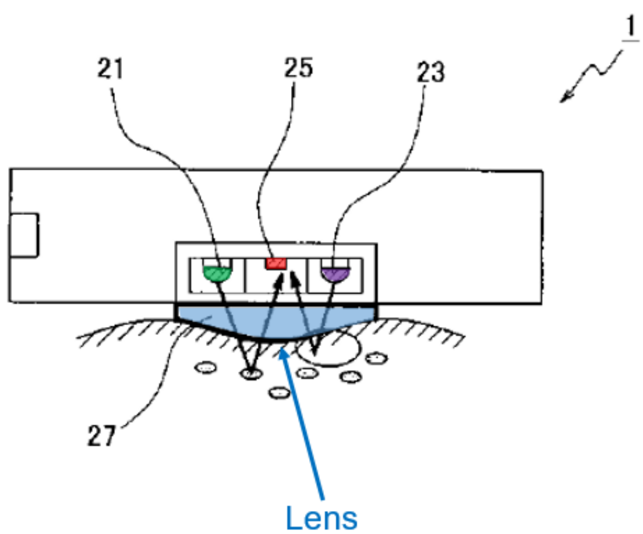
For example, Ohsaki teaches that adding a convex surface to a flat cover (*i.e.*, translucent board 8) can help prevent the device from slipping on the tissue when compared to a flat cover. APPLE-1014, [0025]; APPLE-1003, ¶128. In this context, Aizawa similarly seeks to prevent slippage between the device and the user's wrist—and pursues this objective by pressing its cover (*i.e.*, acrylic transparent plate 6) and trying to improve "adhesion between the wrist 10 and the pulse rate detector 11." APPLE-1006, [0026], [0030].

A POSITA reviewing Aizawa and Ohsaki would have recognized Ohsaki's use of a convex protrusion in its cover as a desirable configuration that would help to further prevent slippage of Aizawa's device. APPLE-1003, ¶128. Thus, a POSITA wanting to achieve improved adhesion between the detector and the skin, as expressly recognized in Aizawa, would have readily modified Aizawa's cover to have a convex protrusion as per Ohsaki. *Id*.

The resulting combination would have provided all remaining elements of claims 1-6, 8-16, 18, and 19 in the same manner as previously described in Ground 1A; APPLE-1003, ¶129.

stance regarding the precise shape of this layer's interface with the skin. Mendelson-1988 does not indicate, for instance, whether the epoxy layer protrudes slightly above the edge of the housing to protect the user's skin from the sharp edges of the housing. Moreover, a POSITA would have realized that the epoxy layer could have been given a shape that would help further advance Mendelson-1988's objective of improving detection efficiency. *See* APPLE-1015, 168, 173; APPLE-1003, ¶135.

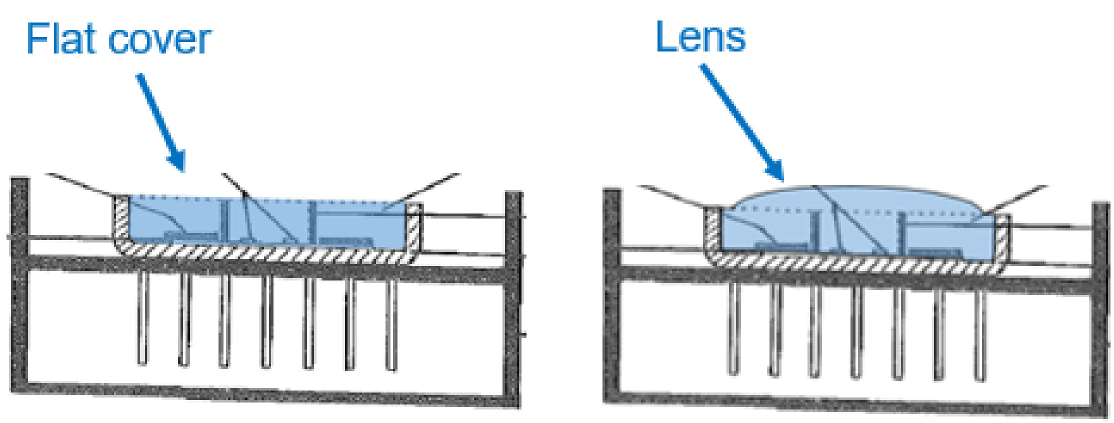
In this context, as described above in Section III.A.2 and shown below, Inokawa provides a pulse sensor with a lens that is positioned over the detectors to "increase the light-gathering ability of the LED as well as to protect the LED or [detector]." APPLE-1008, [0015], [0058].



APPLE-1008, FIG. 2; APPLE-1003, ¶136. Thus, a POSITA would have sought to incorporate an Inokawa-like lens into the cover of Mendelson-1988 to increase the

light collection efficiency, which in turn would lead to more reliable pulse detection. A POSITA would have been particularly interested in making such a modification because Mendelson-1988 is expressly interested in maximizing "reflectance photoplethysmographic signals." APPLE-1015, 173. The lens of Inokawa provides precisely such a benefit to Mendelson-1988's device by refracting and concentrating the incoming light signals that are reflected by the blood. APPLE-1003, ¶137.

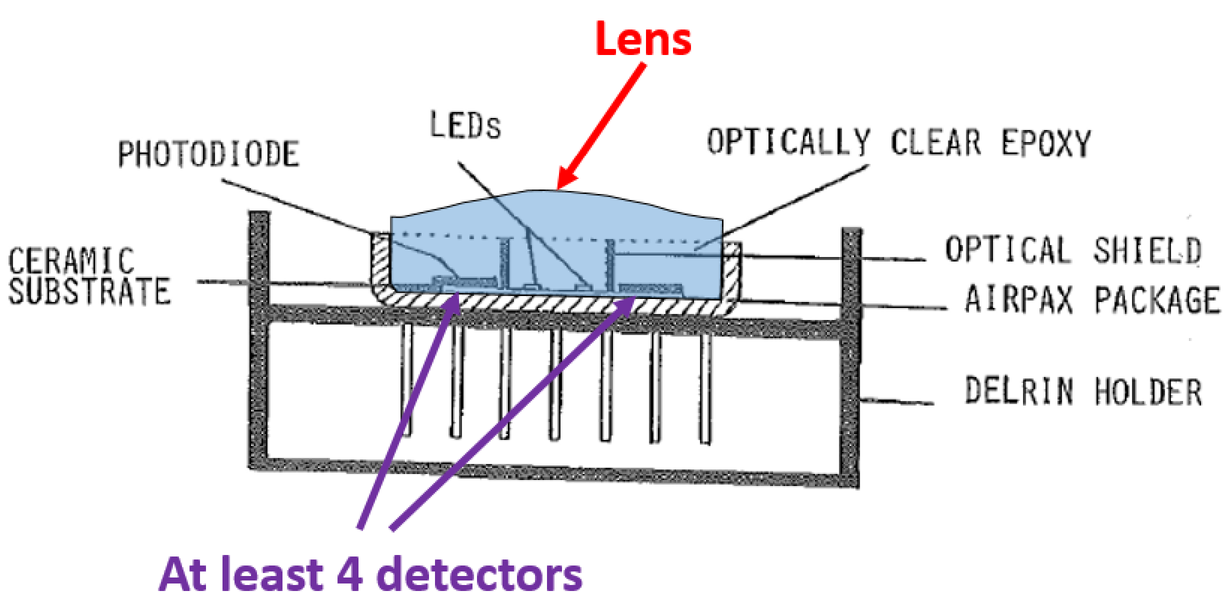
As illustrated below, the device resulting from the obvious combination of Mendelson-1988 and Inokawa would have modified the flat epoxy cover (left) with a lens as per Inokawa (right) to "increase the light-gathering ability." APPLE-1008, [0015]; APPLE-1003, ¶¶138-139.



APPLE-1015, FIG. 2(B).

[1d]: "a lens configured to be located between the tissue of the user and the plurality of detectors when the noninvasive optical physiological sensor is worn by the user, wherein the lens comprises a single outwardly protruding convex surface configured to cause tissue of the user to conform to at least a portion of the single outwardly protruding convex surface when the noninvasive optical physiological sensor worn by the user and during operation of the noninvasive optical physiological sensor."

As discussed above in Section III.C.2 and illustrated below, the combined Mendelson-1988-Inokawa device includes a protruded, convex epoxy cover that acts as a lens and covers the at least four detectors. *See supra* Section III.C.2; APPLE-1003, ¶¶134-143. Thus, reflected light headed toward the detectors is refracted and condensed as it passes through the lens's protrusion. APPLE-1008, [0015], [0058].



APPLE-1015, FIG. 2(B); APPLE-1003, ¶139.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APPLE, INC.,
Petitioner,

v.

MASIMO CORPORATION,
Patent Owner.

Case IPR2021-00208
Patent 10,258,266

PETITIONER'S EXHIBIT LIST

EXHIBITS

APPLE-1001	U.S. Patent No. 10,258,266 to Poeze, et al. ("the '266 patent")
APPLE-1002	Excerpts from the Prosecution History of the '266 patent ("the Prosecution History")
APPLE-1003	Declaration of Dr. Thomas W. Kenny
APPLE-1004	Curriculum Vitae of Dr. Thomas W. Kenny
APPLE-1005	*Masimo Corporation, et al. v. Apple Inc.,* Complaint, Civil Action No. 8:20-cv-00048 (C.D. Cal.)
APPLE-1006	U.S. Pub. No. 2002/0188210 ("Aizawa")
APPLE-1007	JP 2006-296564 ("Inokawa")
APPLE-1008	Certified English Translation of Inokawa and Translator's Declaration
APPLE-1009	U.S. Pat. No. 7,088,040 ("Ducharme")
APPLE-1010	U.S. Pat. No. 8,177,720 ("Nanba")
APPLE-1011 to 1013	RESERVED
APPLE-1014	U.S. Pub. No. 2001/0056243 ("Ohsaki")
APPLE-1015	"Design and Evaluation of a New Reflectance Pulse Oximeter Sensor," Y. Mendelson, et al.; Worcester Polytechnic Institute, Biomedical Engineering Program, Worcester, MA 01609; Association for the Advancement of Medical Instrumentation, vol. 22, No. 4, 1988; pp. 167-173 ("Mendelson-1988")
APPLE-1016	RESERVED
APPLE-1017	RESERVED

APPLE-1018	"Acrylic: Strong, stiff, clear plastic available in a variety of brilliant colors," available at https://www.curbellplastics.com/Research-Solutions/Materials/Acrylic
APPLE-1019 to 1022	RESERVED
APPLE-1023	U.S. Pat. App. Pub. No. 2007/0145255 ("Nishikawa")
APPLE-1024	"Measurement Site and Photodetector Size Considerations in Optimizing Power Consumption of a Wearable Reflectance Pulse Oximeter," Y. Mendelson, et al.; Proceedings of the 25th IEEE EMBS Annual International Conference, 2003; pp. 3016-3019 ("Mendelson-2003")
APPLE-1025	U.S. Pat. No. 6,801,799 ("Mendelson-'799")
APPLE-1026	Declaration of Jacob Munford
APPLE-1027 to 1036	RESERVED
APPLE-1037	*Masimo Corporation, et al. v. Apple Inc.*, Second Amended Complaint, Civil Action No. 8:20-cv-00048 (C.D. Cal.) (Redacted)
APPLE-1038	U.S. Patent No. 8,577,431 to Lamego et al. ("CIP Patent")
APPLE-1039	Order Re Motion to Stay in *Masimo Corporation et al. v. Apple Inc.*, Case 8:20-cv-00048-JVS-JDE, October 13, 2020

Filed July 27, 2022

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APPLE INC.
Petitioner,

v.

MASIMO CORPORATION,
Patent Owner.

IPR2021-00208
Patent 10,258,266

PATENT OWNER'S NOTICE OF APPEAL TO THE U.S. COURT OF APPEALS FOR THE FEDERAL CIRCUIT

Pursuant to 28 U.S.C. § 1295(a)(4)(A), 35 U.S.C. §§ 141(c), 142, and 319, 37 C.F.R. §§ 90.2(a) and 90.3, and Rule 4(a) of the Federal Rules of Appellate Procedure, Patent Owner Masimo Corporation ("Masimo") hereby appeals to the United States Court of Appeals for the Federal Circuit from the Judgment – Final Written Decision (Paper 32) entered on June 1, 2022 (Attachment A) and from all underlying orders, decisions, rulings, and opinions that are adverse to Masimo related thereto and included therein, including those within the Decision Granting Institution of *Inter Partes* Review, entered June 3, 2021 (Paper 7). Masimo appeals the Patent Trial and Appeal Board's determination that claims 1-6, 8-16, 18 and 19 of U.S. Patent 10,258,266 are unpatentable, and all other findings and determinations, including but not limited to claim construction, as well as all other issues decided adverse to Masimo's position or as to which Masimo is dissatisfied in IPR2021-00208 involving Patent 10,258,266.

Masimo is concurrently providing true and correct copies of this Notice of Appeal, along with the required fees, to the Director of the United States Patent and Trademark Office and the Clerk of the United States Court of Appeals for the Federal Circuit.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: July 27, 2022

By: /Jarom Kesler/
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Joseph R. Re (Reg. No. 31,291)
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Attorneys for Patent Owner
Masimo Corporation

Doc Code: TRACK1.REQ
Document Description: TrackOne Request

PTO/AIA/424 (04-14)

CERTIFICATION AND REQUEST FOR PRIORITIZED EXAMINATION UNDER 37 CFR 1.102(e) (Page 1 of 1)

First Named Inventor:	Jeroen Poeze	Nonprovisional Application Number (if known):	Herewith
Title of Invention:	MULTI-STREAM DATA COLLECTION SYSTEM FOR NONINVASIVE MEASUREMENT OF BLOOD CONSTITUENTS		

APPLICANT HEREBY CERTIFIES THE FOLLOWING AND REQUESTS PRIORITIZED EXAMINATION FOR THE ABOVE-IDENTIFIED APPLICATION.

1. The processing fee set forth in 37 CFR 1.17(i)(1) and the prioritized examination fee set forth in 37 CFR 1.17(c) have been filed with the request. The publication fee requirement is met because that fee, set forth in 37 CFR 1.18(d), is currently $0. The basic filing fee, search fee, and examination fee are filed with the request or have been already been paid. I understand that any required excess claims fees or application size fee must be paid for the application.

2. I understand that the application may not contain, or be amended to contain, more than four independent claims, more than thirty total claims, or any multiple dependent claims, and that any request for an extension of time will cause an outstanding Track I request to be dismissed.

3. The applicable box is checked below:

I. ☑ **Original Application (Track One) - Prioritized Examination under § 1.102(e)(1)**

i. (a) The application is an original nonprovisional utility application filed under 35 U.S.C. 111(a). This certification and request is being filed with the utility application via EFS-Web.
---OR---
(b) The application is an original nonprovisional plant application filed under 35 U.S.C. 111(a). This certification and request is being filed with the plant application in paper.

ii. An executed inventor's oath or declaration under 37 CFR 1.63 or 37 CFR 1.64 for each inventor, **or** the application data sheet meeting the conditions specified in 37 CFR 1.53(f)(3)(i) is filed with the application.

II. ☐ **Request for Continued Examination - Prioritized Examination under § 1.102(e)(2)**

i. A request for continued examination has been filed with, or prior to, this form.
ii. If the application is a utility application, this certification and request is being filed via EFS-Web.
iii. The application is an original nonprovisional utility application filed under 35 U.S.C. 111(a), or is a national stage entry under 35 U.S.C. 371.
iv. This certification and request is being filed prior to the mailing of a first Office action responsive to the request for continued examination.
v. No prior request for continued examination has been granted prioritized examination status under 37 CFR 1.102(e)(2).

Signature /Scott Cromar/	Date 2018-12-06
Name (Print/Typed) Scott Cromar	Practitioner Registration Number 65066

Note: *This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4(d) for signature requirements and certifications. Submit multiple forms if more than one signature is required.**

☑ *Total of 1 forms are submitted.

Claim 21. The optical physiological measurement sensor of Claim 18, wherein the lens ~~light concentration window~~ is configured to increase a signal strength per area of the at least four detectors.

Claim 22. The optical physiological measurement sensor of Claim 11, wherein the lens comprises a light concentration window.

2. The following is an examiner's statement of reasons for allowance: The terminal disclaimer to USPN 8,437,825 has been approved on 01/23/2019 to resolve the double patenting issue(s). Schulz et al. (USPN 7,341,559 – applicant cited) teaches a noninvasive optical physiological sensor (Figs. 1-4 and 19 and associated descriptions) comprising: an emitter configured to emit light into tissue of a user (element 400, Figs. 1-4 and 19 and associated descriptions); a detector configured to detect light that has been transmitted through the tissue of the user (elements 800 and 802, Figs. 1, 4, 8, and 19 and associated descriptions); a housing configured to house the detector (Figs. 1-4 and 19 and associated descriptions); and a lens configured to be located between the tissue of the user and the plurality of detectors when the noninvasive optical physiological sensor is proximate the tissue of the user, wherein the lens comprises a single outwardly protruding convex surface (element 1921A and 1920A, Fig. 19B and associated descriptions). Chaiken et al. (USPN 6,223,063 – applicant cited) teaches an optical physiological measurement sensor (Figs. 1-9 and associated descriptions) comprising: a laser configured to emit light into tissue of a user (element 130, Figs. 1-2 and associated descriptions); a circular housing including a planar surface (elements

110 and 140, Figs. 1-2 and associated descriptions); at least four detectors arranged on the planar surface of the circular housing (elements 160, Figs. 1-2 and associated descriptions), wherein the four detectors are arranged in a grid pattern (Figs. 1-2 and associated descriptions); and a lens (element 110, Figs. 1-7 and associated descriptions), wherein at least a portion of the lens protrudes from the housing (elements 150, Figs. 1-3 and associated descriptions). Mannheimer et al. (USPN 5,099,842) teaches a noninvasive optical physiological sensor (Figs. 1-5 and associated descriptions) comprising: a plurality of emitters configured to emit light into tissue of a user (three LEDs in element 120, Figs. 1 and associated descriptions); a detector (element 120, Figs. 1-3 and associated descriptions) configured to detect light that has been transmitted through the tissue of the user; a housing configured to house the detector (Figs. 1-3 and associated descriptions); and light transmissive bumps (elements 100, Figs. 1-3 and associated descriptions) configured to be located between the tissue of the user and the plurality of detectors when the noninvasive optical physiological sensor is proximate the tissue of the user (Figs. 1-3 and associated descriptions). However, the prior art of record does not teach or suggest "*a plurality of detectors configured to detect light that has been transmitted through the tissue of the user, wherein the plurality of detectors comprise at least four detectors;… a lens configured to be located between the tissue of the user and the plurality of detectors when the noninvasive optical physiological sensor is proximate the tissue of the user, wherein the lens comprises a single outwardly protruding convex surface*" and "*a circular housing including a planar surface; at least four detectors arranged on the planar surface of the circular housing, wherein the four detectors are arranged in a grid*

pattern; and a lens forming a cover of the circular housing, wherein at least a portion of the lens protrudes from the housing and the lens comprises a single convex surface", in combination with the other claimed elements/ steps.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHU CHUAN LIU whose telephone number is (571)270-5507. The examiner can normally be reached on M-Th (8am-6pm).

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jacqueline Cheng can be reached on (571) 272-5596. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent of:	Poeze et al.	
U.S. Patent No.:	10,258,266	Attorney Docket No.: 50095-0007IP1
Issue Date:	April 16, 2019	
Appl. Serial No.:	16/212,537	
Filing Date:	December 6, 2018	
Title:	MULTI-STREAM DATA COLLECTION SYSTEM FOR NONINVASIVE MEASUREMENT OF BLOOD CONSTITUENTS	

DECLARATION OF DR. THOMAS W. KENNY

Declaration

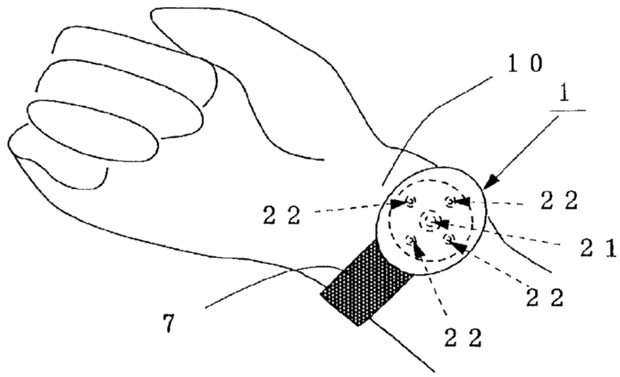
I declare that all statements made herein on my own knowledge are true and that all statements made on information and belief are believed to be true, and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable under Section 1001 of Title 18 of the United States Code.

By: ______________________

Thomas W. Kenny, Ph.D.

Aizawa's sensor is adapted to be worn by the user by being attached to the user's wrist. *Id.*, [0026].

FIG. 2



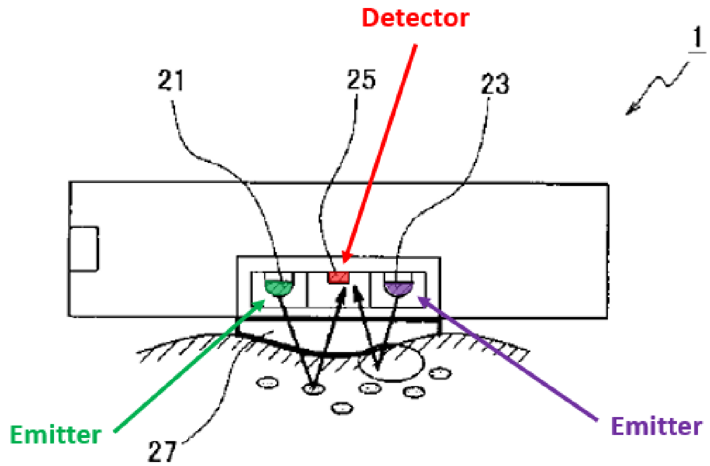
APPLE-1006, FIG. 2

[1a] a plurality of emitters configured to emit light into tissue of a user;

69. As noted above, Aizawa teaches a pulse wave sensor having multiple detectors disposed circularly around an emitter. APPLE-1006, [0023]. As also noted, Aizawa considers the use of multiple emitters but does not expressly talk about using multiple emitters at different wavelengths. *Id.*, [0033].

70. Here, I note that Inokawa teaches the use of two different types of emitters "such as an infrared LED or a green LED" and further teaches that "work can be divided between the various means, with an infrared LED used to detect vital signs and transmit vital sign information, and a green LED used to detect pulse." APPLE-1008, [0014], [0044], [0058], [0059]. As shown below, Inokawa teaches

use of a first emitter (LED 21, colored green) and a second emitter (LED 23, colored purple). *Id.*, [0058], [0059].

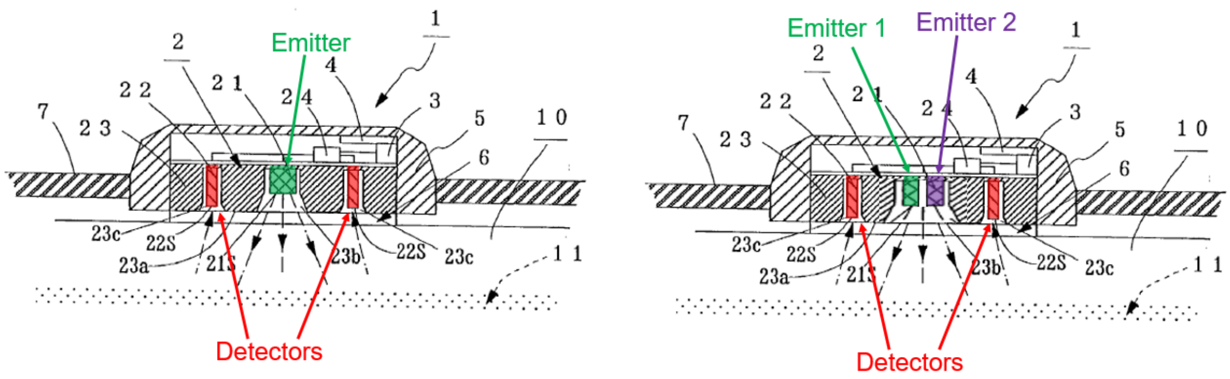


APPLE-1008, FIG. 2

71. A POSITA in possession of both Aizawa and Inokawa would have realized that Inokawa's teachings concerning the use of two different emitters operating at different wavelengths would be applicable to Aizawa as well to yield similar benefits. For example, Aizawa only mentions using a single wavelength of light, but Inokawa teaches the benefits of dividing the role of a single LED into two different LEDs "with an infrared LED used to detect vital signs and transmit vital sign information, and a green LED used to detect pulse." APPLE-1008, [0014], [0044], [0058], [0059].

72. Thus, a POSITA would have recognized that providing an additional emitter of a different wavelength to Aizawa, as per Inokawa, would enable Aizawa's device to, for instance, (1) use the existing infrared LED to detect body motion and

(2) use the added green LED to detect pulse. *Id.*, [0059]. While it's possible that adding more emitters to Aizawa may lead to increased power consumption, a POSITA seeking to improve detection performance would have nevertheless looked to Inokawa's multi-emitter setup to achieve enhanced performance benefits. *Id.* Indeed, various other prior art pulse sensing devices teach, similar to Inokawa, using a first LED emitting at below 600 nm (*e.g.*, green) to measure blood flow and a second LED emitting at above 600 nm (*e.g.*, infrared) to measure body movement. *See, e.g.,* APPLE-1010, 8:45-50. The added ability to measure body movement in this manner will allow for a more reliable measurement that can, for instance, take into account and correct for inaccurate readings related to body movement. *Id.* For instance, the signal component corresponding to body movement can be subtracted from the pulse signal to help better isolate the desired pulse data. *Id.* Thus, applying the teachings of Inokawa, a POSITA would have been motivated and found it obvious to divide the single emitter of Aizawa, into two emitters operating at two different wavelengths, as demonstrated below, to be able to detect both pulse and body movement signals.



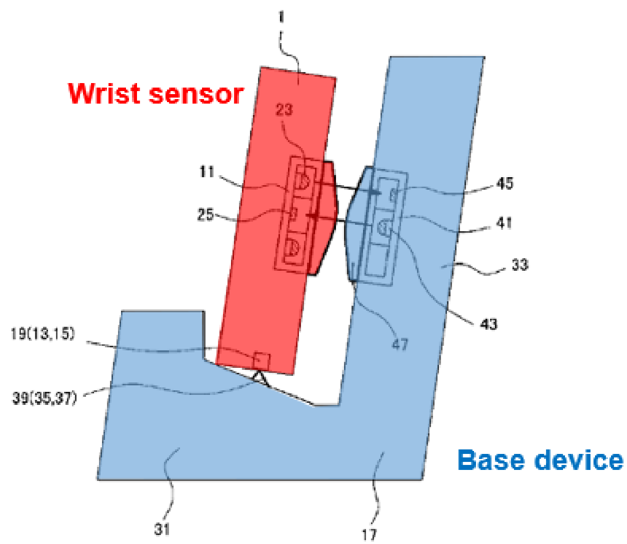
APPLE-1006, FIG. 1(b)

73. More specifically, one of ordinary skill would have replaced Aizawa's LED 21 with two LEDs, each emitting a different wavelength. As suggested by Inokawa, one of ordinary skill would have recognized that this would improve Aizawa's sensor by enabling it to account for motion load through use of the second LED, by detecting and recording body motion in addition to blood flow. APPLE-1008, [0006], [0028], [0035]. Because, Aizawa already contemplates adding additional emitters, a POSITA would have known how to make the changes needed, for example concerning circuitry, to add another LED in this manner. APPLE-1006, [0032]. While the exemplary drawings I've provided above show two smaller emitters replacing a larger emitter, which is simply a matter of design choice to a POSITA in circuit design and assembly, a similar effect could be achieved by simply enlarging the emitter cavity and including two larger emitters, which is again a simple matter of design choice.

74. Such a modification would have amounted to nothing more than the use of a known technique to improve similar devices in the same way, and combining prior art elements according to known methods to yield predictable results. Indeed, a POSITA would have recognized that applying Inokawa's teachings about two emitters having different wavelengths to Aizawa's sensor would have led to predictable results without significantly altering or hindering the functions performed by Aizawa's sensor. That is, a POSITA would have been motivated to provide the well-known feature of providing multiple emitters to a pulse sensor to achieve the predictable benefits that Inokawa's arrangement provides.

75. In addition to the rationale provided above, Inokawa provides an additional, or alternative, reason to add another emitter to Aizawa.

76. First, I note that Aizawa contemplates uploading data from its wrist sensor to an external base device but does not go into details about how such data transmission would be implemented. APPLE-1006, [0015], [0023], [0035]. Here, a POSITA would have been able to fill this gap by looking to Inokawa, which, as shown below, teaches a base device 17 (colored blue) that both charges and receives data from the pulse sensor 1 (colored red). APPLE-1008, [0060].

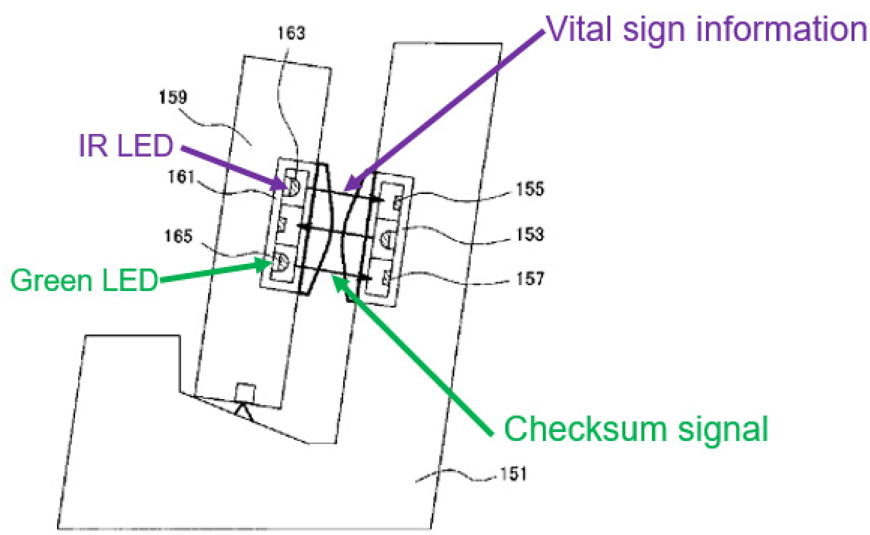


APPLE-1008, FIG. 3

77. Inokawa further teaches that, by using the sensor's infrared emitter to transmit data, "it is not necessary to use a wireless communication circuit or to establish connections via communication cable, which makes it possible to easily transmit vital sign information with few malfunctions and with a simple structure." APPLE-1008, [0007]. In view of such teaching, a POSITA would have been motivated and found it obvious and straightforward to incorporate Inokawa's base device and LED-based data transmission into Aizawa's sensor to, for instance, "make[] it possible to transmit vital sign information to the base device 17 accurately, easily, and without malfunction." *Id.,* [0077]. A POSITA would have also recognized that adding Inokawa's base device and LED-based data transmission scheme to Aizawa would allow Aizawa to upload data from its sensor

without having to use a separate cable and without having to incorporate a separate RF circuit into Aizawa's wrist sensor. APPLE-1008, [0007].

78. Here, I note that Inokawa's sensor is able to transmit data using only a single LED, for example operating at infrared wavelength. APPLE-1008, [0062]. However, as shown below, Inokawa also teaches that it's possible to use two different LEDs operating at different wavelengths to improve data transmission accuracy, namely by using a second LED operating at green wavelength, for instance, to transmit checksum information such that "the accuracy of data can be increased." *Id.*, [0111], [0044], [0048].



APPLE-1008, FIG. 19

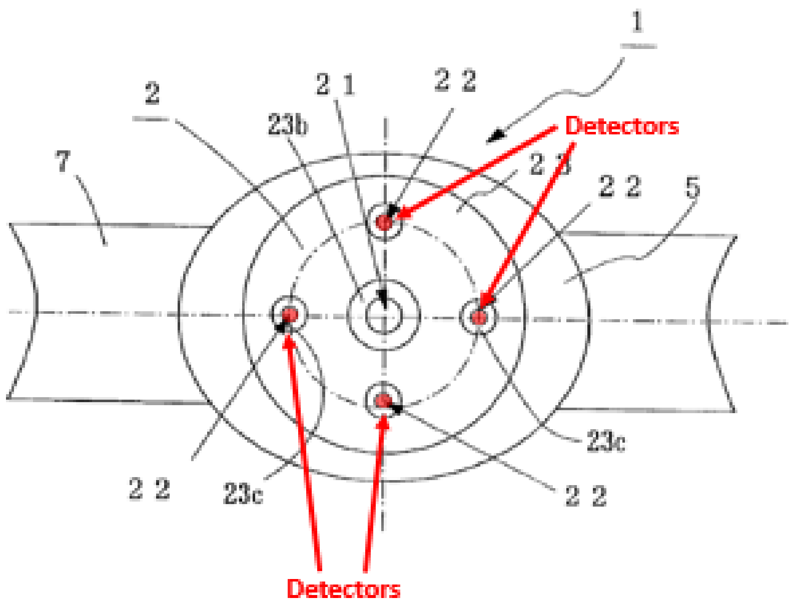
79. Accordingly, a POSITA would have found it obvious to supplement Aizawa's IR LED with an additional green LED, as per Inokawa, improve accuracy of data transmission from its sensor.

80. Indeed, a POSITA would have found it obvious to modify Aizawa with Inokawa in this manner because doing so entails the use of known solutions (*i.e.*, using a dual-LED system to more accurately transmit pulse data from a sensor to a base device) to improve similar systems and methods in the same way. For instance, a POSITA would have recognized that applying Inokawa's base device and dual-LED-based data transmission to Aizawa's sensor would have led to the predictable result of more accurate and convenient data transmission without significantly altering or hindering the functions performed by Aizawa's sensor. As such, a POSITA would have had a reasonable expectation of success in making this modification, and would have reasonably expected to reap benefits of simple and accurate data transmission. Indeed, it was common practice in the pulse oximeter field to centrally locate multiple emitters of different wavelengths, for example as further demonstrated by Mendelson-1988. APPLE-1015, 168; FIG. 2(A).

81. Thus, for reasons provided above, a POSITA would have found it obvious to split the single emitter of Aizawa into two emitters as in Inokawa in order to (i) acquire body motion information for improved pulse detection and/or (ii) more reliably transmit information from the sensor to a base device with less error. APPLE-1008, [0007], [0014], [0044], [0048], [0058], [0059], [0060], [0062], [0077], [0111].

[1b] a plurality of detectors configured to detect light that has been attenuated by tissue of the user, wherein the plurality of detectors comprise at least four detectors;

82. As illustrated below, Aizawa teaches "four photodetectors 22 disposed around the light emitting diode 21 symmetrically on a circle concentric to the light emitting diode 21." APPLE-1006, [0029], [0024], [0032].

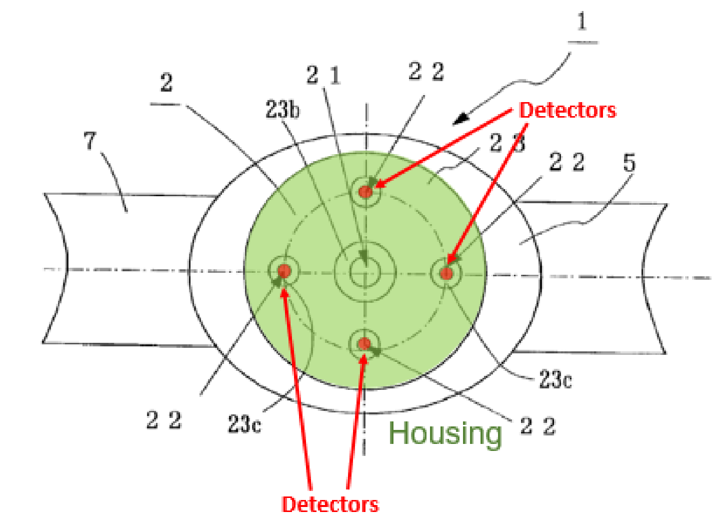


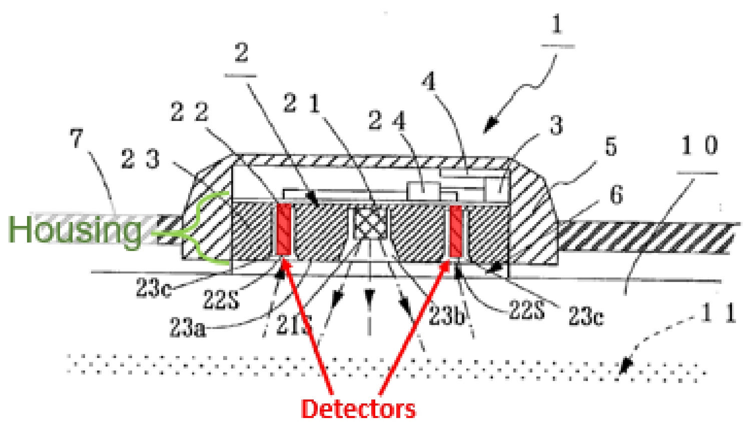
APPLE-1006, FIG. 1(a)

83. Moreover, Aizawa's photodetectors 22 are designed to detect light that is "reflected by a red corpuscle running through the artery 11 of the wrist 10 ... so as to detect a pulse wave." APPLE-1006, [0027]. Aizawa subsequently "detect[s] a pulse wave by amplifying the outputs of the photodetectors 22." *Id.*, [0023]. Thus, the detectors of Aizawa "detect light that has been attenuated by tissue of the user." *Id.*, [0027].

[1c] a housing configured to house at least the plurality of detectors; and

84. Aizawa teaches "a holder 23 for storing the above light emitting diode 21 and the photodetectors 22." APPLE-1006, [0023], [0024]. As further described below for [2], Aizawa also teaches a two-dimensional surface that supports the holder 23. *Id.* Thus, as shown below the holder and the flat surface are part of the housing element as required by this claim.



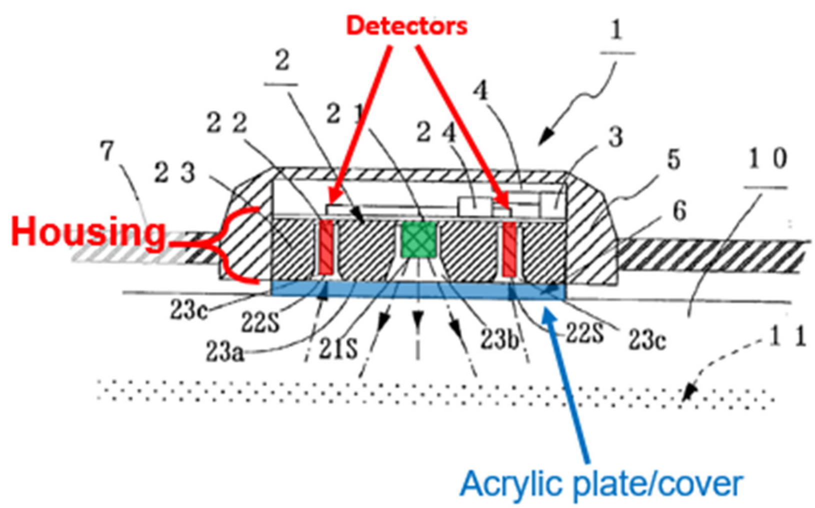


APPLE-1006, FIGS. 1(1)-(b)

[1d] a lens configured to be located between the tissue of the user and the plurality of detectors when the noninvasive optical physiological sensor is

worn by the user, wherein the lens comprises a single outwardly protruding convex surface configured to cause tissue of the user to conform to at least a portion of the single outwardly protruding convex surface when the noninvasive optical physiological sensor worn by the user and during operation of the noninvasive optical physiological sensor.

85. As explained above and shown below, Aizawa teaches a light permeable cover in the form of an acrylic transparent plate 6 (colored blue) that is mounted at the detection face 23a over at least a portion of the housing to cover the at least four detectors (colored red). APPLE-1006, [0023].

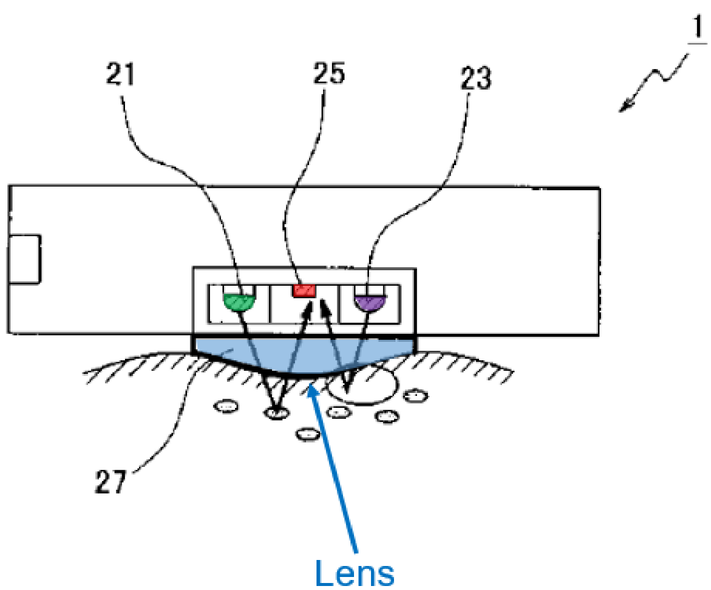


APPLE-1006, FIG. 1(b) (annotated), [0023]

86. However, the acrylic plate of Aizawa is flat and is not described as including a lens. But a POSITA would have been motivated and known how to modify the flat shape of Aizawa's acrylic plate to achieve a particular, desired objective. For example, Aizawa teaches that its light permeable cover (*i.e.*, acrylic transparent plate) helps improve "detection efficiency," but does not otherwise provide more details about how, for instance based on its shape or material properties, such an

effect may be achieved. APPLE-1006, [0030]. Indeed, a POSITA would have readily recognized that the shape of Aizawa's plate could be modified based on well-known techniques to help achieve Aizawa's objective of improving detection efficiency. APPLE-1006, [0013], [0030], [0032]; APPLE-1009 at 3:46-51.

87. As one example, a POSITA would have been able to look to Inokawa to enhance light collection efficiency, in particular by modifying the light permeable cover of Aizawa to include a convex protrusion that acts as a lens, as per Inokawa. APPLE-1008, FIG. 2. As illustrated below, Inokawa teaches a side lens 27 (colored blue) that is positioned between a pulse sensor and the user's skin. *Id.*

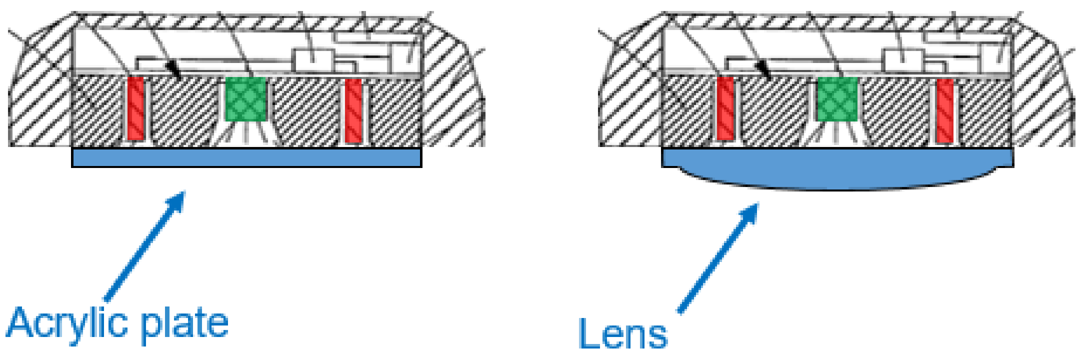


APPLE-1008, FIG. 2

88. Inokawa teaches that the "lens makes it possible to increase the light-gathering ability of the LED." *Id.*, [0015]. Thus, a POSITA would have sought to incorporate a convex, lens structure as in Inokawa into Aizawa's acrylic plate to

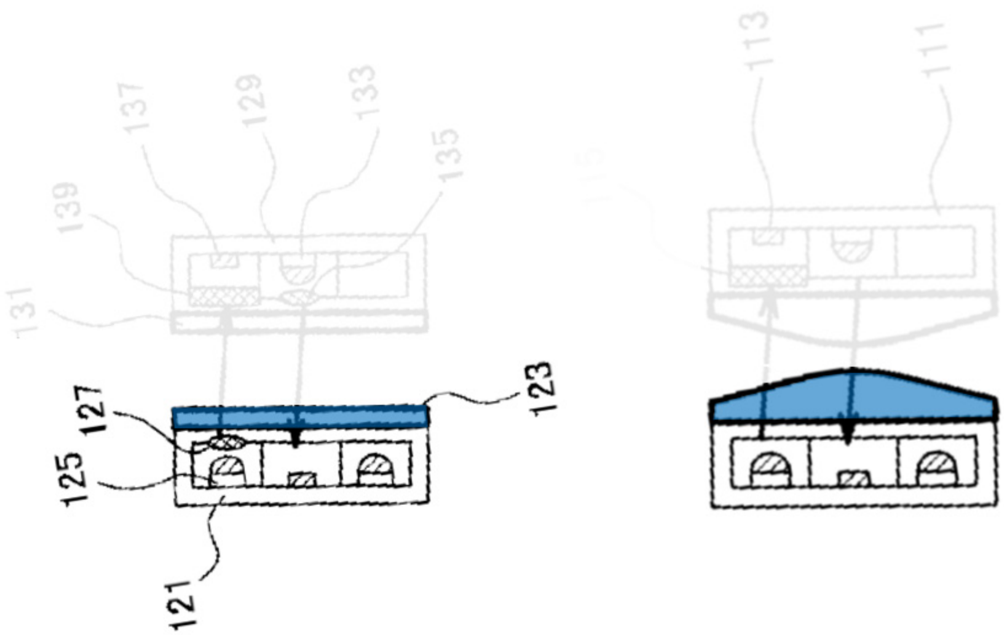
thereby increase light collection efficiency, in turn leading to more reliable pulse wave detection. The lens of Inokawa can provide this benefit by refracting and concentrating the light coming in through Aizawa's acrylic plate after being reflected by the blood and attenuated by the tissue of the user. Incidentally, because the path of light is reversible, the light collection function of Inokawa's lens would work the same way regardless of whether light is emitted toward the center (and detected by a centrally located photodiode) or emitted away from the center (and detected by a peripherally located photodiode).

89. In more detail, a POSITA would have found it obvious to combine the teachings of Aizawa and Inokawa such that the flat cover (left) of Aizawa is modified to include a lens (right) as per Inokawa in order to "increase the light-gathering ability." APPLE-1008, [0015]. Indeed, by positioning a lens above the optical components of Aizawa, as shown below, the modified cover will allow more light to be gathered and refracted toward the light receiving cavities of Aizawa, thereby further increasing the light-gathering ability of Aizawa beyond what is achieved through the tapered cavities. APPLE-1006, [0012], [0024].



APPLE-1006, FIG. 1(b)

90. A POSITA would have further understood *how* to incorporate Inokawa's lens into Aizawa's cover, and further would have expected such a modification to succeed given the high degree of overlap between the two references. For example, as shown below, Inokawa teaches that its light permeable cover can be flat (left) so that "the surface is less prone to scratches," or alternatively be in the form of a lens (right) to "increase the light-gathering ability of the LED." APPLE-1008, [0015], [0016]. That is, depending on the desired objective of the user (*e.g.*, less scratches or improved light-gathering), the shape of the cover can be readily modified. Moreover, by choosing the material of the protrusion to be scratch-resistant, such as glass, it would have been obvious for a POSITA to achieve both benefits at once.

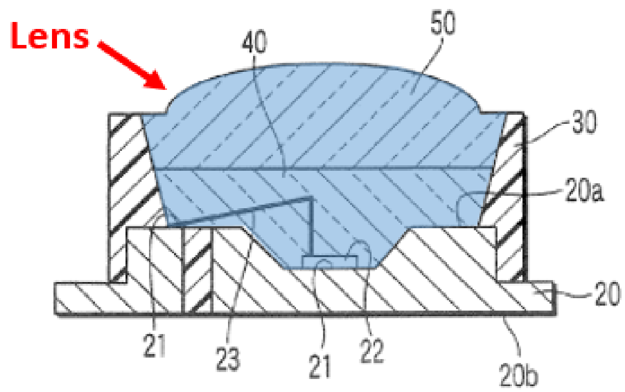


APPLE-1008, FIG. 17 (left), FIG. 16 (right)

91. A POSITA would have further recognized that the acrylic material used to make Aizawa's acrylic transparent plate 6 can be easily formed to include a lens. *See* APPLE-1009 at 3:46-51, FIG. 1; APPLE-1023, FIG. 6, [0022], [0032], [0035]. Indeed, many prior art references of this period, such as Nishikawa (shown below) demonstrate exactly how such a lens may be incorporated into a molded cover. APPLE-1023, FIG. 6, [0022], [0032], [0035]. In other words, a POSITA would have known that acrylic is a transparent material that can be readily transformed into various forms, including a lens, as needed due to its easy molding properties. *Id.* Thus, a POSITA preferring improved light collection efficiency over reduced susceptibility to scratches could have been able to easily modify Aizawa's cover to be a lens as per Inokawa. *Id.* This would have been a mere design choice. Indeed,

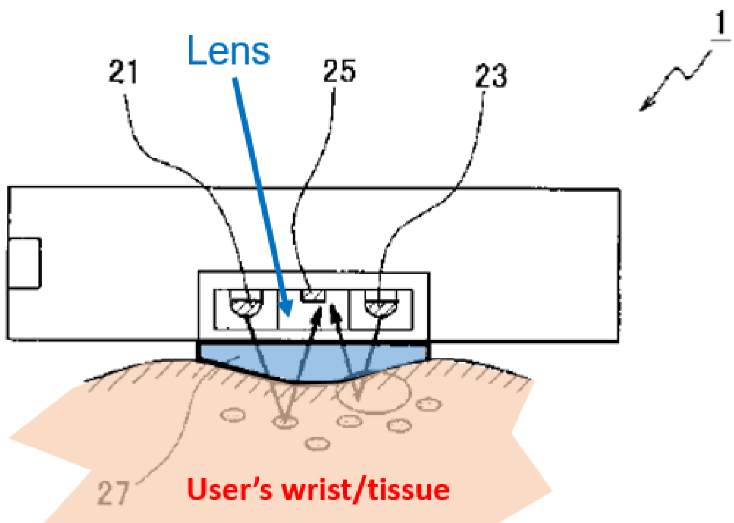
only a routine knowledge of sensor design and assembly, which were well within the skill of a POSITA, would be required to perform such modifications. Thus, to achieve the goal of improving light collection efficiency, which both Aizawa and Inokawa share, a POSITA would have been able to, with a reasonable expectation of success, modify Aizawa's light permeable cover to include a lens as taught by Inokawa.

FIG. 6



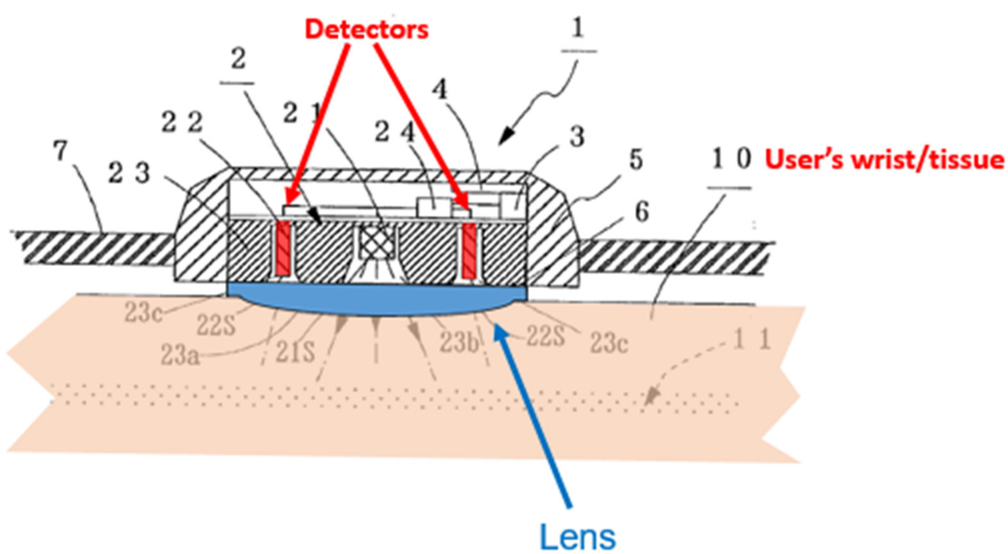
APPLE-1023, FIG. 6

92. Moreover, the light permeable cover of Aizawa is designed to be pressed toward the skin of the user with some pressure. APPLE-1006, [0006], [0026]. Being pressed into the skin in this manner will cause the tissue to conform to at least a portion of the protruding surface because the skin is less rigid than the light permeable cover, for example as demonstrated below by Inokawa where it can be seen that the user's tissue has deformed around the protruded surface of the cover.



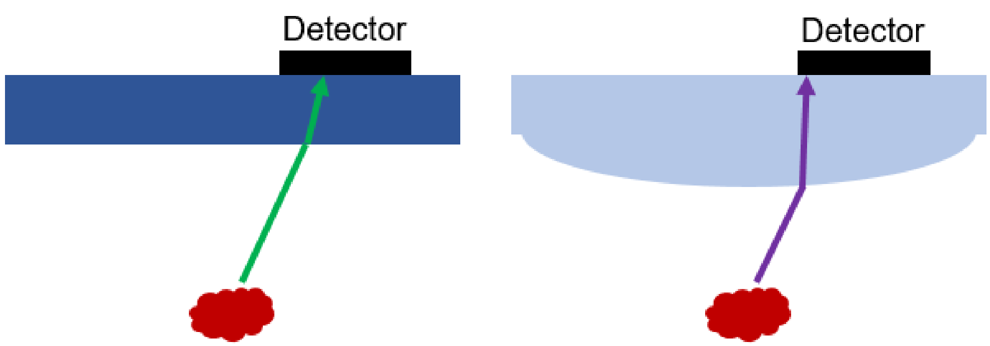
APPLE-1008, FIG. 2

93. Similarly, when the lens of Inokawa is incorporated into Aizawa as discussed above for element [1d], the protrusion will cause the tissue of the user, which is less rigid than the protrusion, to conform around the convex surface of the lens/protrusion when the device is pressed against the tissue during use.

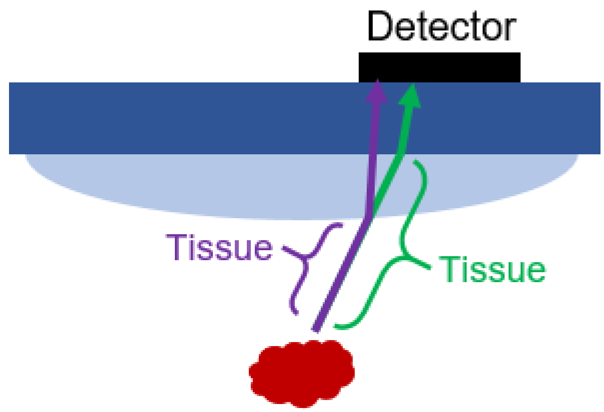


APPLE-1006, FIG. 1(b)

102. In more detail, I noted above for [1d] how the lens of Inokawa, which is used to modify Aizawa's cover, provides a condensing function by refracting the light passing through it. APPLE-1008, [0015], [0058]. As demonstrated through my drawings below, where the left figure shows the length of non-refracted light and the right figure shows the length of refracted light, such refraction of the incoming reflected light can shorten the path of the light before it reaches the detector. This is because the incoming light is "condensed" toward the center. APPLE-1008, [0015], [0058]. Thus, as demonstrated by the drawings below, both the total length of travel as well as the length through the tissue can be reduced.



103. Laying these two drawings on top of each other, as shown below, the shortened path length within the tissue for the purple (refracted) line can be clearly seen compared to the path length within the tissue of the green (non-refracted) line. The shortened *total* path length of the purple line compared to the green line can also be seen. Accordingly, the Aizawa-Inokawa combination, through its use of a condensing lens between the tissue and the detectors, serves to reduce a mean path length of light traveling to the at least four detectors.



104. [[INTENTIONALLY LEFT BLANK]]

G. Claim 8

[8] The noninvasive optical physiological sensor of claim 4, wherein the lens is configured to increase a signal strength per area of the plurality of detectors.

105. As explained above with respect to [1d], the Aizawa-Inokawa combination includes provides a convex lens that helps enhance the device's light-gathering ability. APPLE-1008, [0015], FIG. 2. Indeed, a POSITA would have known that a lens, as in Inokawa and as incorporated into Aizawa, would condense incoming light onto the detectors, thus increasing the signal strength per area of the detectors (since each detector area will receive more incoming light signals).

H. Claim 9

[9pre] An optical physiological measurement sensor comprising:

106. As I explained above in ¶ 68 for [1pre], the analysis for which I fully incorporate herein, the Aizawa-Inokawa combination discloses or renders obvious this element.

[9a] a plurality of emitters configured to emit light into tissue of a user;

124. In the Aizawa-Inokawa combination I described above in ¶¶ 85-93 for [1d], the cover provides a window that allows light to pass through to the detectors. APPLE-1006, FIG. 1(b); APPLE-1008, [0015], [0058]. Indeed, the transparent cover in the Aizawa-Inokawa combination is held in place and surrounded by opaque structural elements of Aizawa, such that a portion of the lens is a window that allows light to pass through. A POSITA would have understood the housing of Aizawa, including its holder 23, to be opaque in order to be able to prevent unwanted ambient light from entering inside the housing. Moreover, because the lens acts as a light concentrator that improves the light-gathering ability of the modified device, the modified cover acts as a window that has a light concentrating function—*i.e.,* a light concentration window.

IX. GROUND 1B – Claims 1-6, 8-16, 18, and 19 Are Rendered Obvious by Aizawa in view of Inokawa and Ohsaki

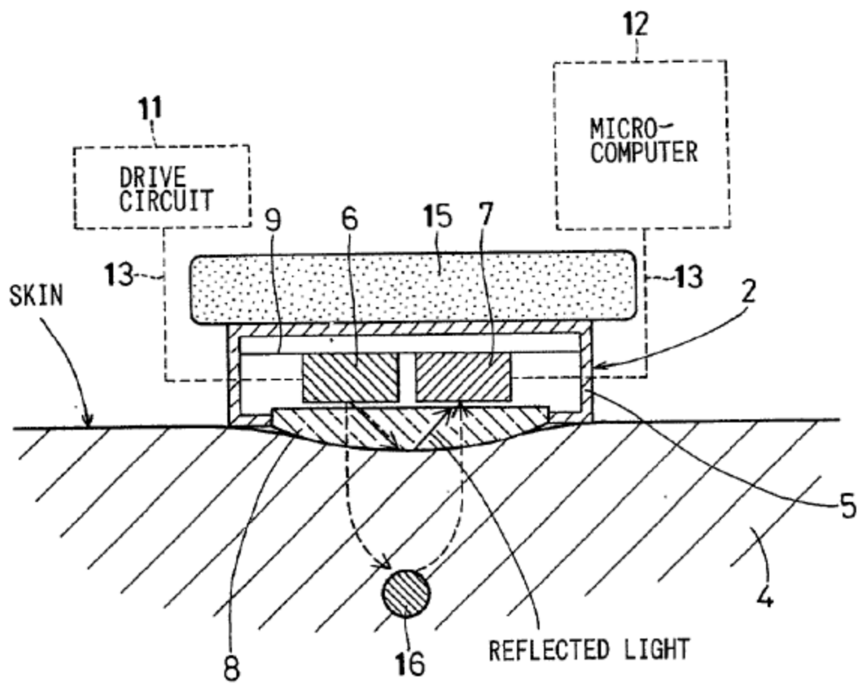
A. Claims 1-6, 8-16, 18, and 19

125. As I explained above in ¶¶ 85-93 with respect to element [1d], a POSITA would have been motivated to incorporate a lens-like protrusion of Inokawa into the cover of Aizawa to increase the light collection efficiency.

126. Ohsaki (APPLE-1014), which I briefly described above in ¶¶ 63-64, provides an alternative/additional rationale for why a POSITA would have modified the flat shape of Aizawa's acrylic plate into a protruded lens as per element [1d].

127. Among other things, Ohsaki teaches that adding a convex surface to its translucent board 8 (*i.e.*, light permeable cover) can help prevent the device from slipping on the tissue of the wearer compared to using a flat cover without such a protrusion. APPLE-1014, [0025].

FIG. 2



APPLE-1014, FIG. 2

128. Minimizing slippage between a user-worn sensor device and the tissue of the user was indeed a well-known objective in such devices. For example, Aizawa teaches using its acrylic transparent plate 6 (*i.e.*, light permeable cover) to improve "adhesion between the wrist 10 and the pulse rate detector 11." APPLE-1006, [0026], [0030]. While Aizawa doesn't discuss whether the shape of its acrylic plate could be modified to achieve this objective, a POSITA in possession of both

Aizawa and Ohsaki would have recognized that Ohsaki's addition of a convex protrusion to its light permeable cover could be similarly implemented in Aizawa's device to help achieve the two references' shared goal of minimizing slippage. *Id.* In other words, a POSITA seeking to achieve improved adhesion between the detector and the skin, as expressly recognized in Aizawa, would have been motivated and readily able to modify Aizawa's acrylic plate to have a convex shape as in Ohsaki. This would have allowed Aizawa's sensor device to remain better adhered to the skin and thereby increase its light-collecting efficiency. APPLE-1006, [0026], [0030]; APPLE-1014, [0025]. Additionally, a POSITA would have appreciated that the lens/protrusion in the Aizawa-Inokawa combination as detailed above in ¶¶ 89-98 would have provided a similar anti-slippage advantage due to the lens's convex shape, thereby providing an additional motivation for a POSITA to make the above-noted modification of Aizawa in view of Inokawa's lens.

129. The resulting Aizawa-Inokawa-Ohsaki combination satisfies all remaining elements of claims 1-6, 8-16, 18, and 19 in the same manner as previously described in Ground 1A, which is herein incorporated by reference.

X. GROUND 2 – Claims 1-6, 8-16, 18, and 19 Are Rendered Obvious by Mendelson-1988 in view of Inokawa

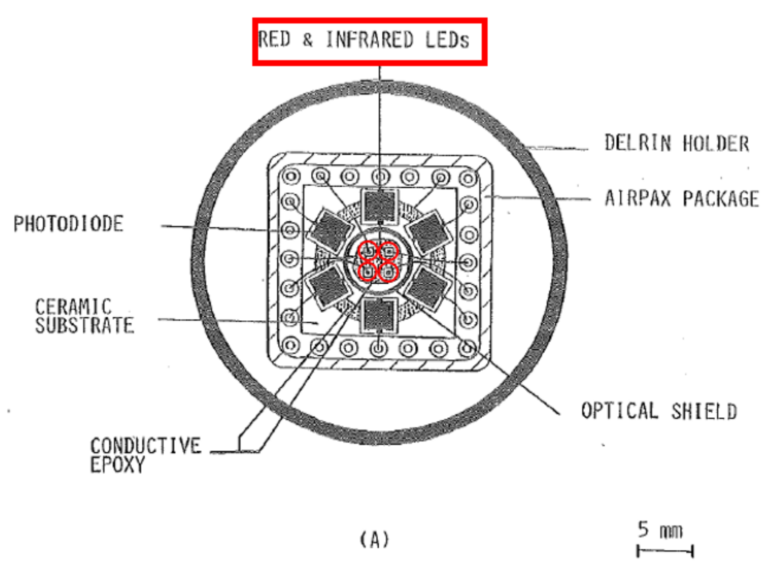
A. Claim 1

[1pre] A noninvasive optical physiological sensor comprising

130. Mendelson-1988 discloses "a new optical reflectance sensor suitable for noninvasive monitoring of arterial hemoglobin oxygen saturation with a pulse oximeter." APPLE-1015, Abstract, 167, 172. Hemoglobin oxygen saturation is one of the physiological parameters expressly mentioned in the '628 patent. APPLE-1001, Claim 16.

[1a] a plurality of emitters configured to emit light into tissue of a user;

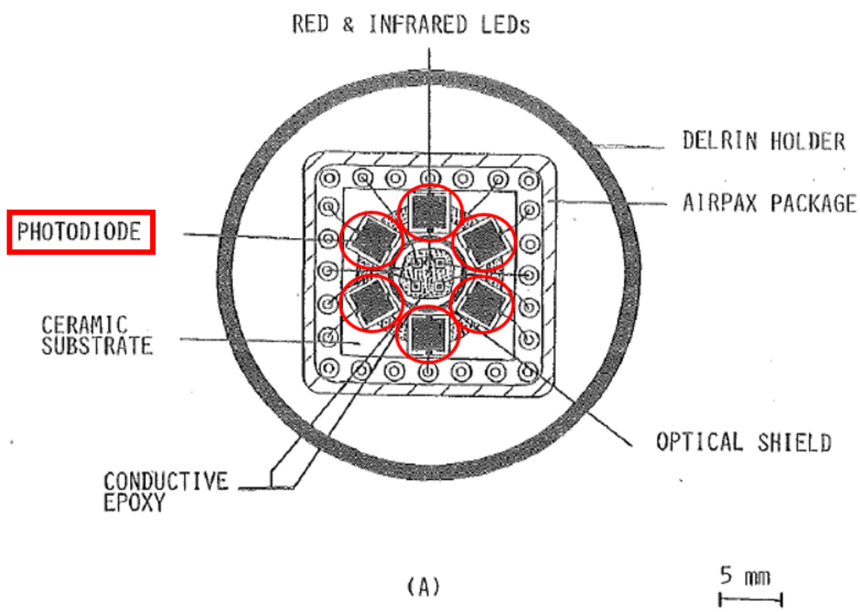
131. As illustrated below, Mendelson-1988 teaches using two red and two infrared LEDs that are centrally located within the device. APPLE-1015, 168. Red and infrared LEDs emit different wavelengths of light. *Id.* The light is emitted into the tissue of the user to be "diffused by the skin in all directions." *Id.*



APPLE-1025, FIG. 2(A)

[1b] a plurality of detectors configured to detect light that has been attenuated by tissue of the user, wherein the plurality of detectors comprise at least four detectors;

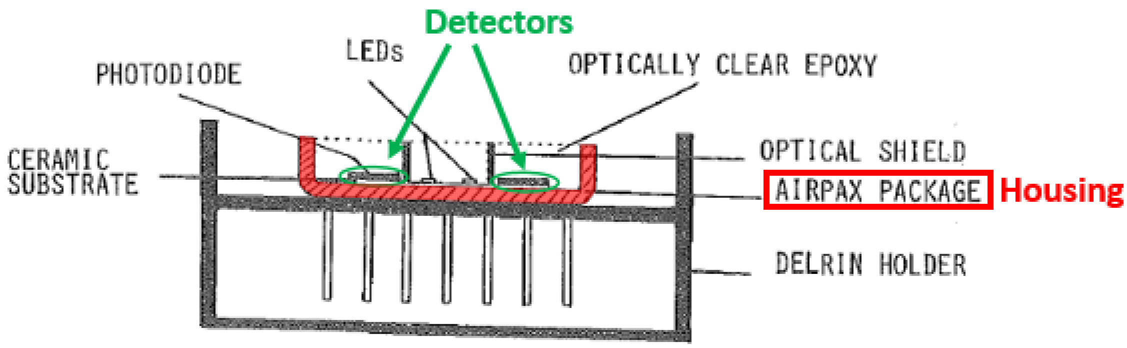
132. Mendelson-1988 teaches "six silicon photodiodes ... arranged symmetrically in a hexagonal configuration," as shown below, thus providing at least four detectors as claimed. APPLE-1015, 168. Output from the detectors are "current pulses ... which correspond to the red and infrared light intensities reflected from the skin" and are processed to respective photoplethysmographic waveforms. APPLE-1015, 169.



APPLE-1015, FIG. 2(A)

[1c] a housing configured to house at least the plurality of detectors; and

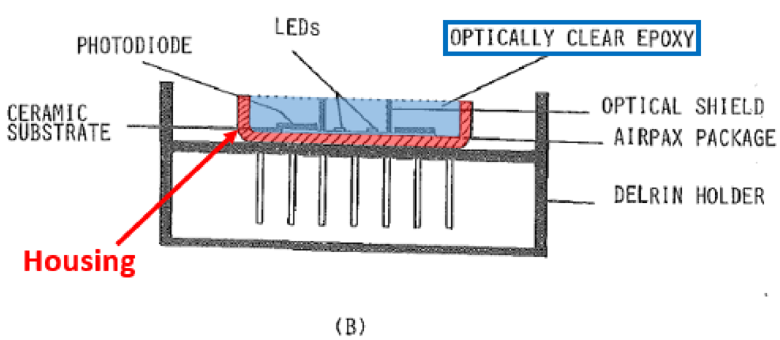
133. As I show below, Mendelson-1988 teaches that its emitters and detectors are mounted on a ceramic substrate and housed within an AIRPAX microelectronic package, which corresponds to the claimed housing. APPLE-1015, 168.



APPLE-1015, FIG. 2(B);

[1d] a lens configured to be located between the tissue of the user and the plurality of detectors when the noninvasive optical physiological sensor is worn by the user, wherein the lens comprises a single outwardly protruding convex surface configured to cause tissue of the user to conform to at least a portion of the single outwardly protruding convex surface when the noninvasive optical physiological sensor worn by the user and during operation of the noninvasive optical physiological sensor.

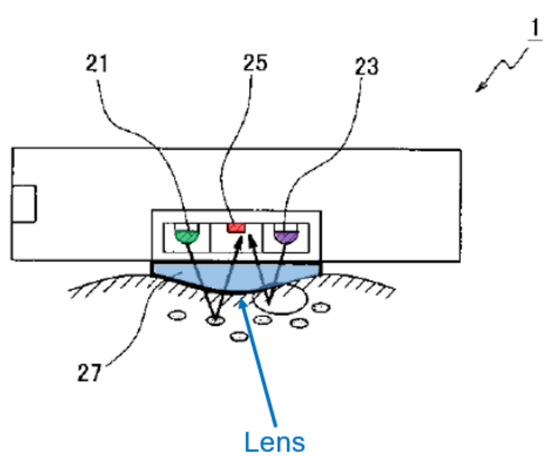
134. As shown below, Mendelson-1988 teaches encapsulating its emitters and detectors, which are within the housing (red), with an optically clear epoxy layer (blue). APPLE-1015, 168. This epoxy layer, therefore, provides a cover that is arranged above the housing and covers the detectors. *Id.*



APPLE-1015, FIG. 2(b)

135. However, beyond Mendelson-1988's disclosure that this cover is made from "optically clear epoxy," Mendelson-1988 does not provide further details. Among other things, the precise shape of this layer, for instance whether it's completely flat or slightly curved, is not mentioned. It's also not mentioned whether this epoxy layer protrudes slightly above the rest of the housing to, for instance, protect the user's skin from coming in direct contact with any sharp edges of the housing. Yet a POSITA would have recognized that the shape of the epoxy layer may be formed as needed to help further Mendelson'1988's goal of improving detection efficiency. APPLE-1015, 168, 173.

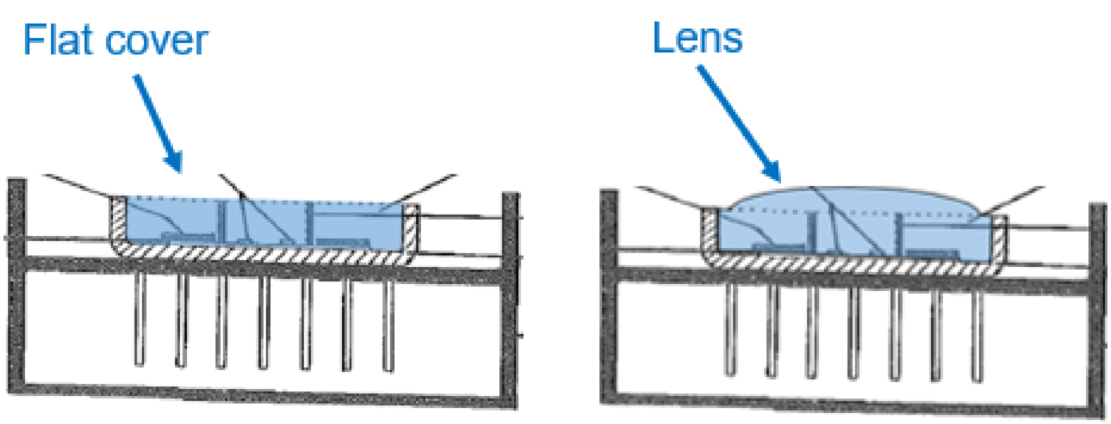
136. Indeed, as I described above, Inokawa teaches a similarly configured pulse sensor as in Mendelson-1988 but one in which a lens is positioned over the detectors to "increase the light-gathering ability of the LED as well as to protect the LED or [detector]." APPLE-1008, [0015], [0058].



APPLE-1008, FIG. 2

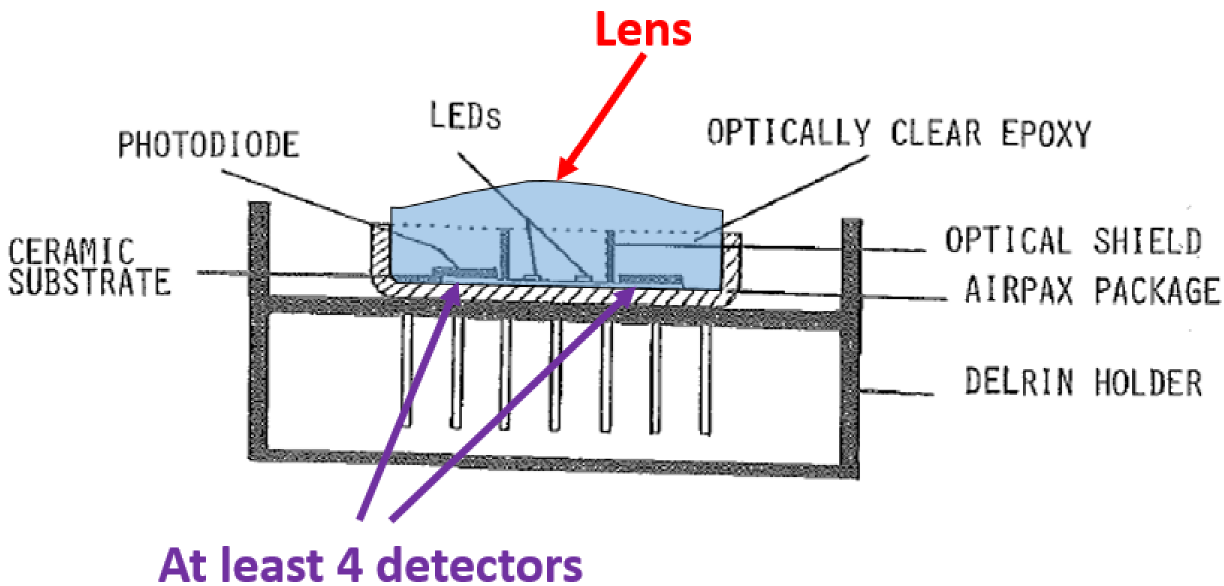
137. Accordingly, a POSITA would have been motivated to incorporate the lens of Inokawa into to cover of Mendelson-1988 in order to increase the light collection efficiency. A POSITA would have been particularly interested in making such a modification because Mendelson-1988 shares a similar goal of maximizing "reflectance photoplethysmographic signals." APPLE-1015, 173. The lens of Inokawa provides precisely this benefit to Mendelson'1988's device by providing a protective cover that further refracts and concentrates the incoming light beams to thereby enhance the light collection efficiency and, by extension, the signal to noise ratio. APPLE-1008, [0015], [0058].

138. Indeed, as illustrated below, the device resulting from this combination of Mendelson-1988 and Inokawa would have modified the flat epoxy cover (left) with a curved one as per Inokawa (right) to thereby "increase the light-gathering ability." APPLE-1008, [0015].



APPLE-1015, FIG. 2(B)

139. In this way, reflected light headed toward the detectors is refracted and condensed as it passes the lens/protrusion. APPLE-1008, [0015], [0058].



APPLE-1015, FIG. 2(B)

140. A POSITA would have understood how to implement Inokawa's cover in Mendelson-1988 with a reasonable expectation of success based, among other things, on the significant overlap between these two references. Indeed, the above-described modification would require only routine knowledge of sensor design and assembly, which were well within the skill of a POSITA prior to the Critical Date.

141. Moreover, a POSITA would have easily understood how to modify the epoxy layer of Mendelson-1988 to achieve the desired shape. Indeed, Nishikawa, shown below, teaches that a clear epoxy layer as in Mendelson-1988 can be molded into a lens. APPLE-1023, [0022], [0032], [0035].

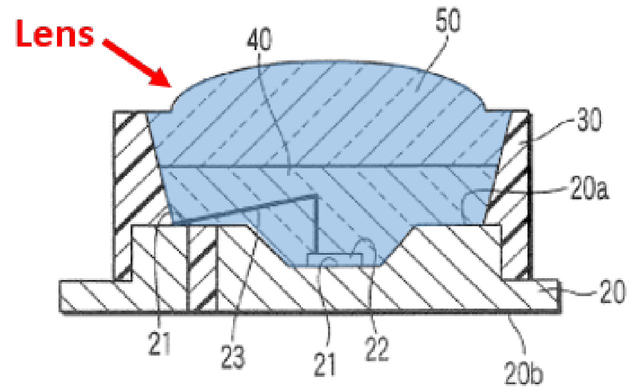


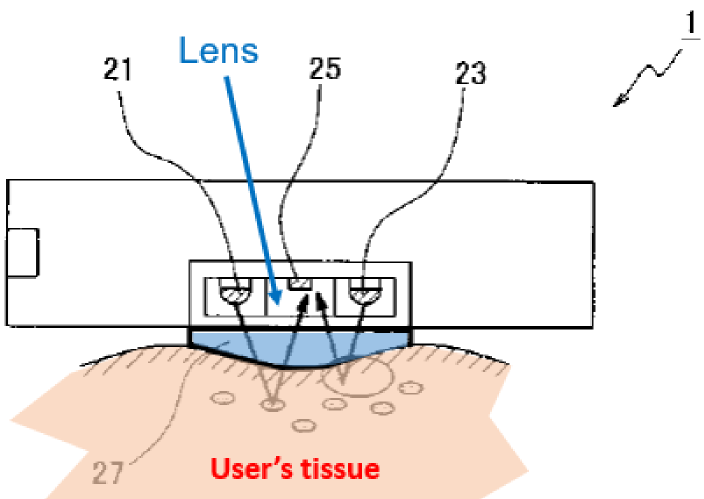
FIG. 6

APPLE-1023, FIG. 6

142. Notably, both the optical encapsulation layer of Mendelson-1988 and the lens layer of Nishikawa are made from the same material, optically clear epoxy, and thus the interface between the encapsulation portion and the lens portion will not adversely affect the optical performance of the modified system. APPLE-1023, [0037]. Thus, to help achieve Mendelson-1988's and Inokawa's shared goal of improving light collection efficiency, a POSITA would have been motivated and able to modify Mendelson-1988's epoxy cover to be a lens as per Inokawa with a reasonable expectation of success.

143. Moreover, the epoxy cover of Mendelson-1988 is designed to be attached directly to the user's skin. APPLE-1015, 169. Being pressed into the skin in this manner will cause the tissue of the user to conform to at least a portion of the outwardly protruding convex surface because the skin is more pliable than the light permeable cover, for example as demonstrated below by Inokawa where it can be

seen that the user's tissue has deformed around the convex surface of the cover. APPLE 1008, [0099], [0107], FIGS. 2, 3, 16, 19.



APPLE-1008, FIG. 2

B. Claim 2

[2] The noninvasive optical physiological sensor of claim 1,wherein the plurality of detectors are arranged on a two-dimensional surface of the housing.

144. As discussed for [1c] and further illustrated below, Mendelson-1988 discloses that its emitters and detectors are mounted on a ceramic substrate, which corresponds to the claimed two-dimensional surface, and further housed within an AIRPAX microelectronic package, which corresponds to the claimed:

US008177720B2

(12) **United States Patent**
Nanba et al.

(10) **Patent No.: US 8,177,720 B2**
(45) **Date of Patent: May 15, 2012**

(54) **APPARATUS FOR DETECTING VITAL FUNCTIONS, CONTROL UNIT AND PULSE WAVE SENSOR**

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(73) Assignees: **DENSO CORPORATION**, Kariya (JP); **Toshiaki Shiomi**, Nagoya (JP)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 1342 days.

(21) Appl. No.: **11/802,607**

(22) Filed: **May 24, 2007**

(65) **Prior Publication Data**

US 2007/0282227 A1 Dec. 6, 2007

(30) **Foreign Application Priority Data**

May 31, 2006 (JP) 2006-152354

(51) **Int. Cl.**
A61B 5/02 (2006.01)

(52) **U.S. Cl.** **600/483**; 600/484

(58) **Field of Classification Search** 600/483, 600/486, 500–504
See application file for complete search history.

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JP	A-2003-038460	2/2003
JP	A-2005-199078	7/2005

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Office Action mailed on Jul. 5, 2011 in the corresponding Japanese Patent application No. 2006-152354 (English translation enclosed).

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Primary Examiner — Miranda Le
Assistant Examiner — Tho Tran
(74) *Attorney, Agent, or Firm* — Posz Law Group, PLC

(57) **ABSTRACT**

An apparatus for detecting vital functions has a pulse wave sensor attachable to a body and a control unit. The control unit checks if amplitude of pulse wave signals produced from the pulse wave sensor varies. The control unit further checks if a large change in the amplitude during a systolic phase of a pulse wave corresponding to the systolic phase of the heart. If a first large change in the amplitude during a diastolic phase of a pulse wave corresponding to the diastolic phase of the heart, it is highly probable that a motion artifact has occurred. Therefore, a motion artifact flag is set. Next, it is checked if the amplitude in the next diastole is changing by more than 30%. if it is presumed that the occurrence of cough is highly probable, a cough flag is set. if it is neither the motion artifact nor the cough, then a yawn flag is set.

26 Claims, 10 Drawing Sheets

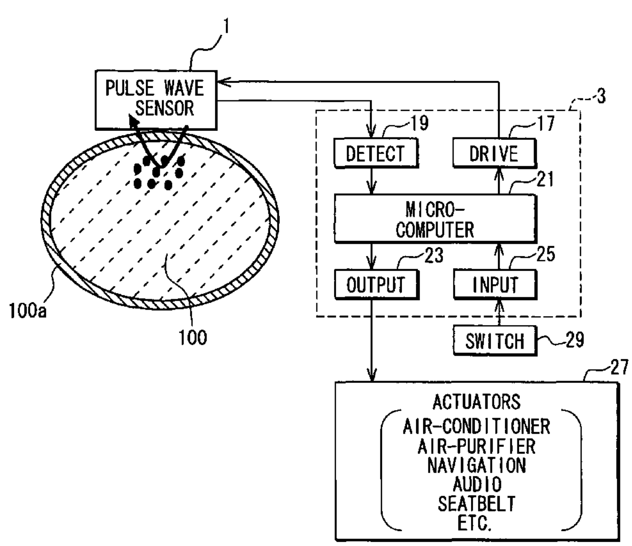


FIG. 1A

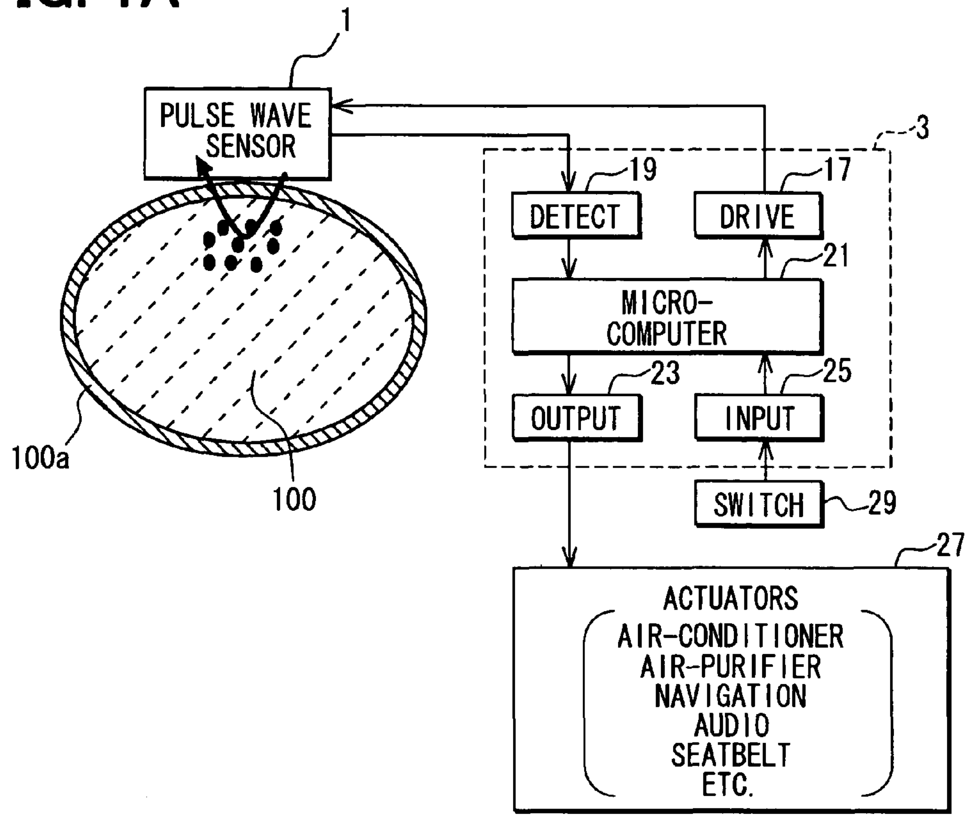

1
PULSE WAVE SENSOR
3
19
DETECT
17
DRIVE
21
MICRO-COMPUTER
23
OUTPUT
25
INPUT
SWITCH
29
27
ACTUATORS
AIR-CONDITIONER
AIR-PURIFIER
NAVIGATION
AUDIO
SEATBELT
ETC.
100a
100

FIG. 1B

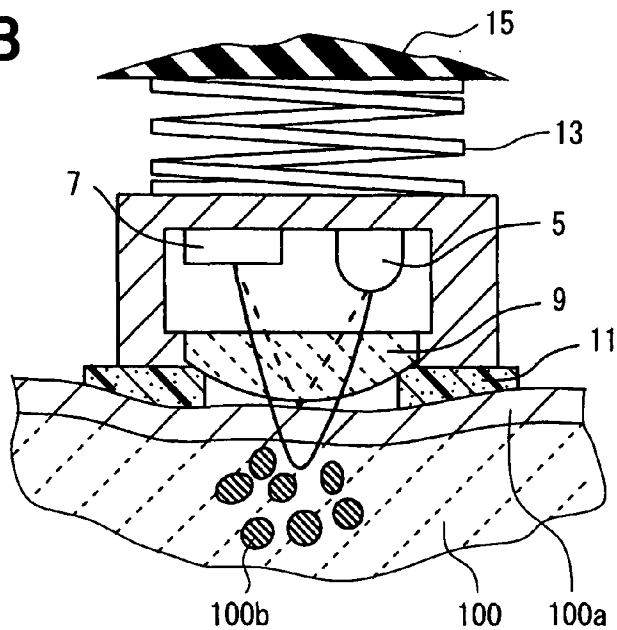

15
13
7
5
9
11
100b
100
100a

FIG. 2A

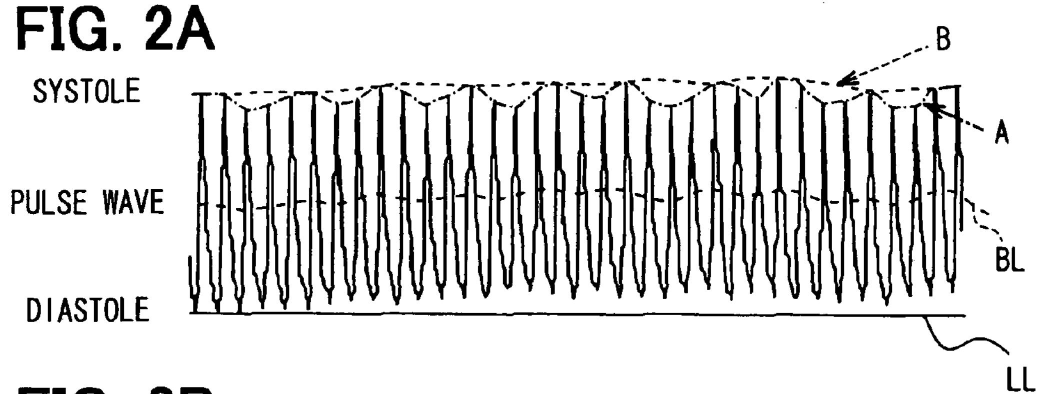


FIG. 2B

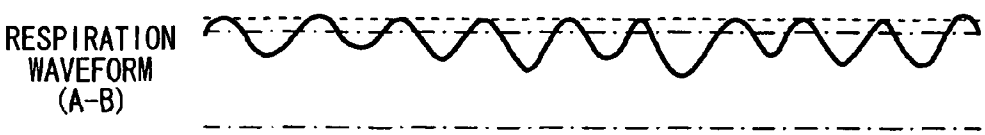


FIG. 3A

MOTION ARTIFACT

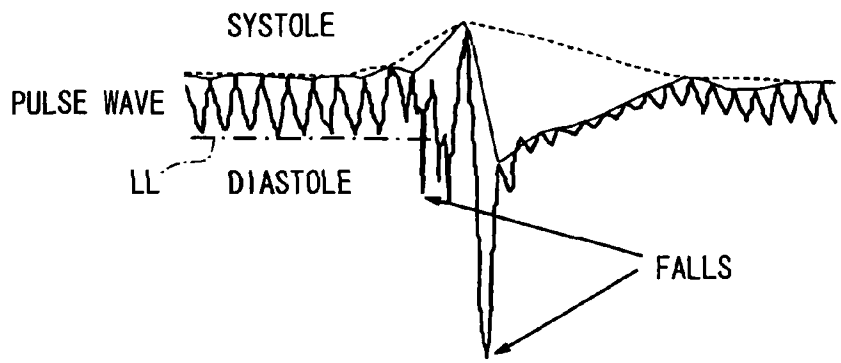


FIG. 3B

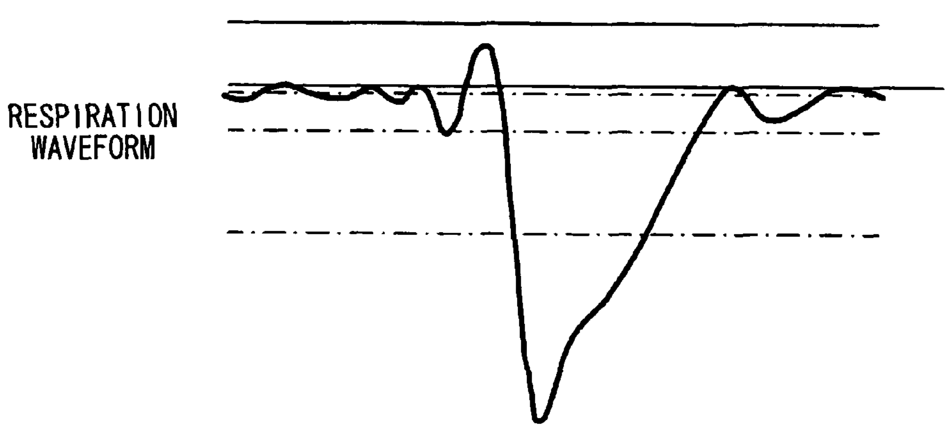


FIG. 4A

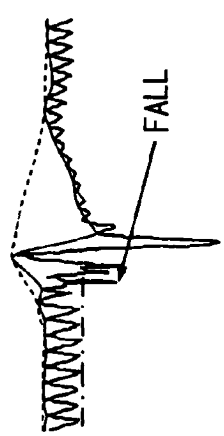


FIG. 4B

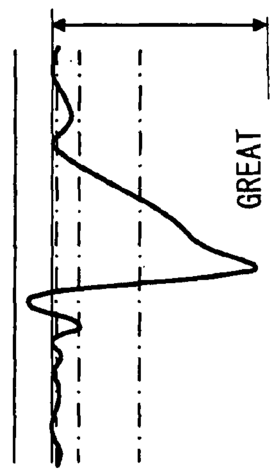


FIG. 4C

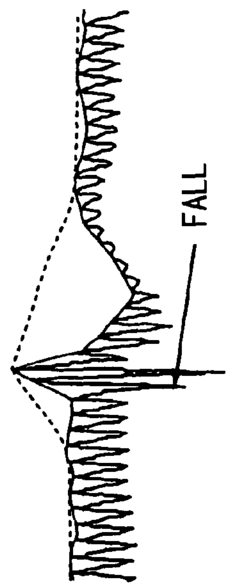


FIG. 4D

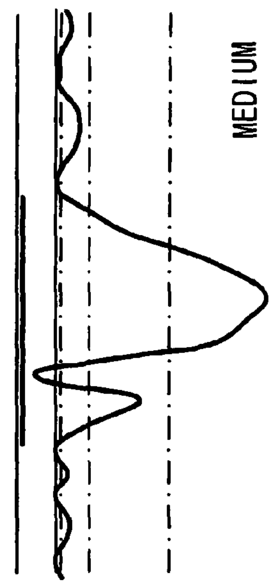


FIG. 4E

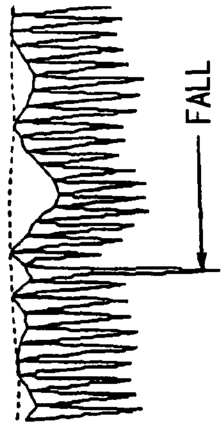


FIG. 4F

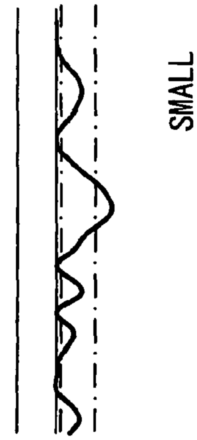


FIG. 5A

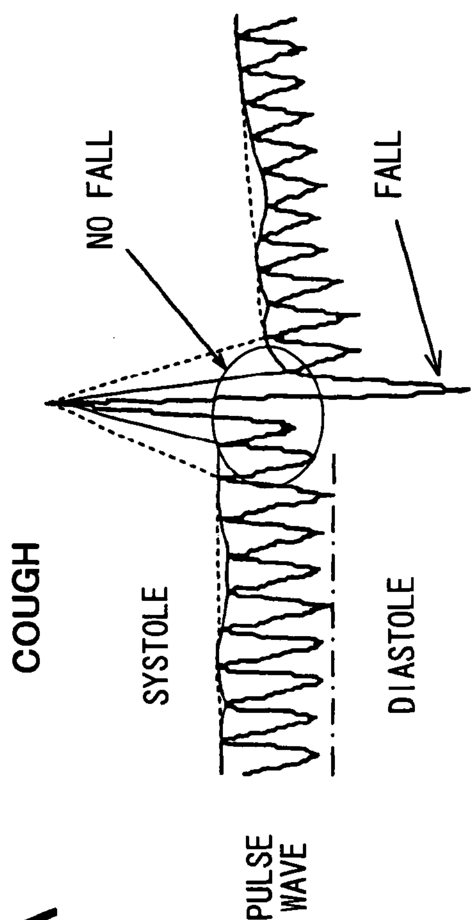

COUGH
NO FALL
FALL
SYSTOLE
DIASTOLE
PULSE WAVE

FIG. 5B

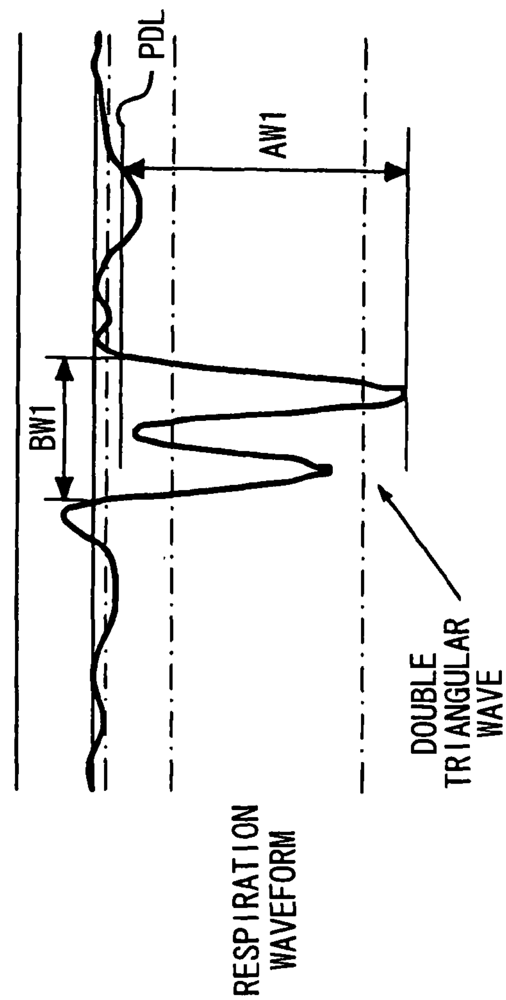

PDL
AW1
BW1
RESPIRATION WAVEFORM
DOUBLE TRIANGULAR WAVE

FIG. 6A

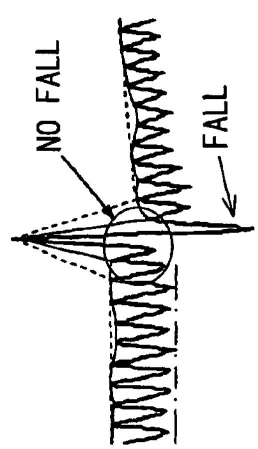


FIG. 6B

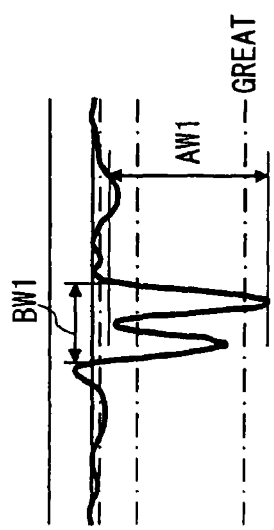


FIG. 6C

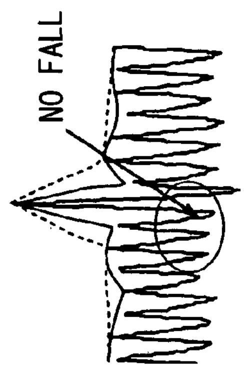


FIG. 6D

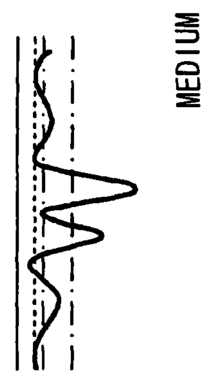


FIG. 6E

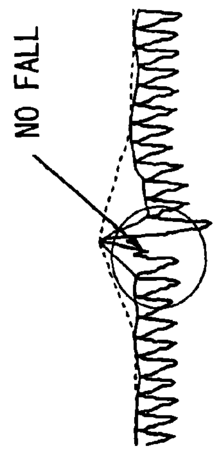


FIG. 6F

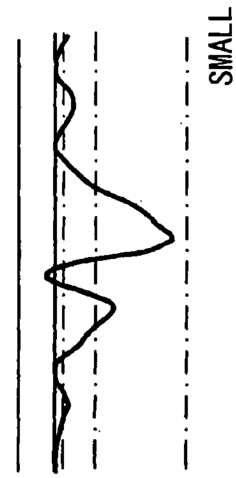


FIG. 7A

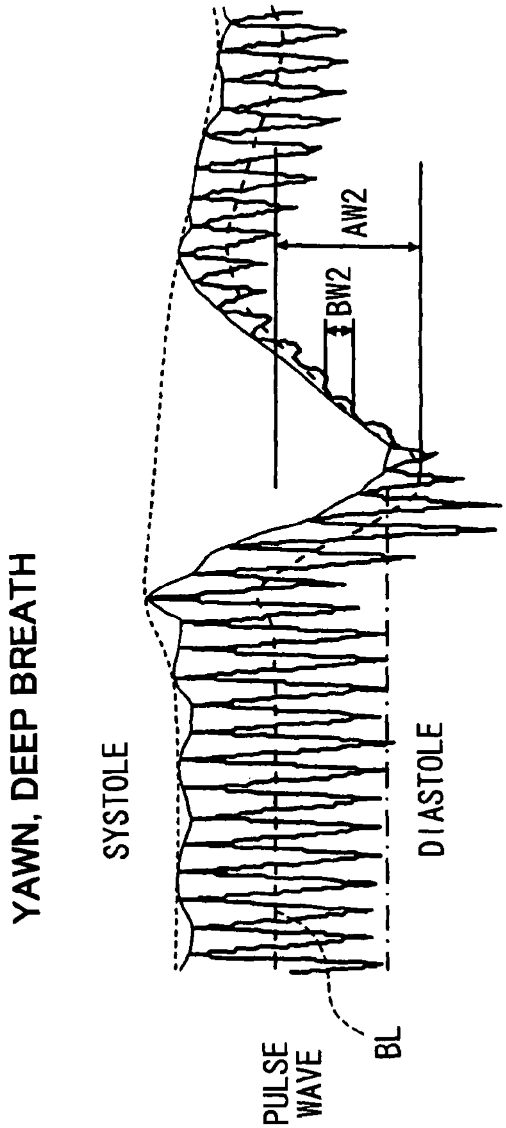
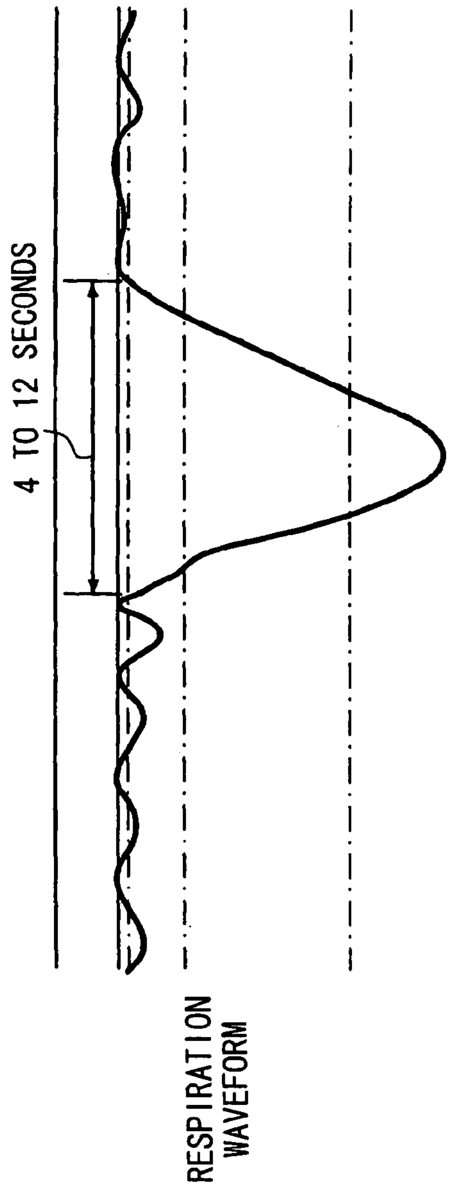

YAWN, DEEP BREATH
SYSTOLE
DIASTOLE
AW2
BW2
PULSE WAVE
BL

FIG. 7B


4 TO 12 SECONDS
RESPIRATION WAVEFORM

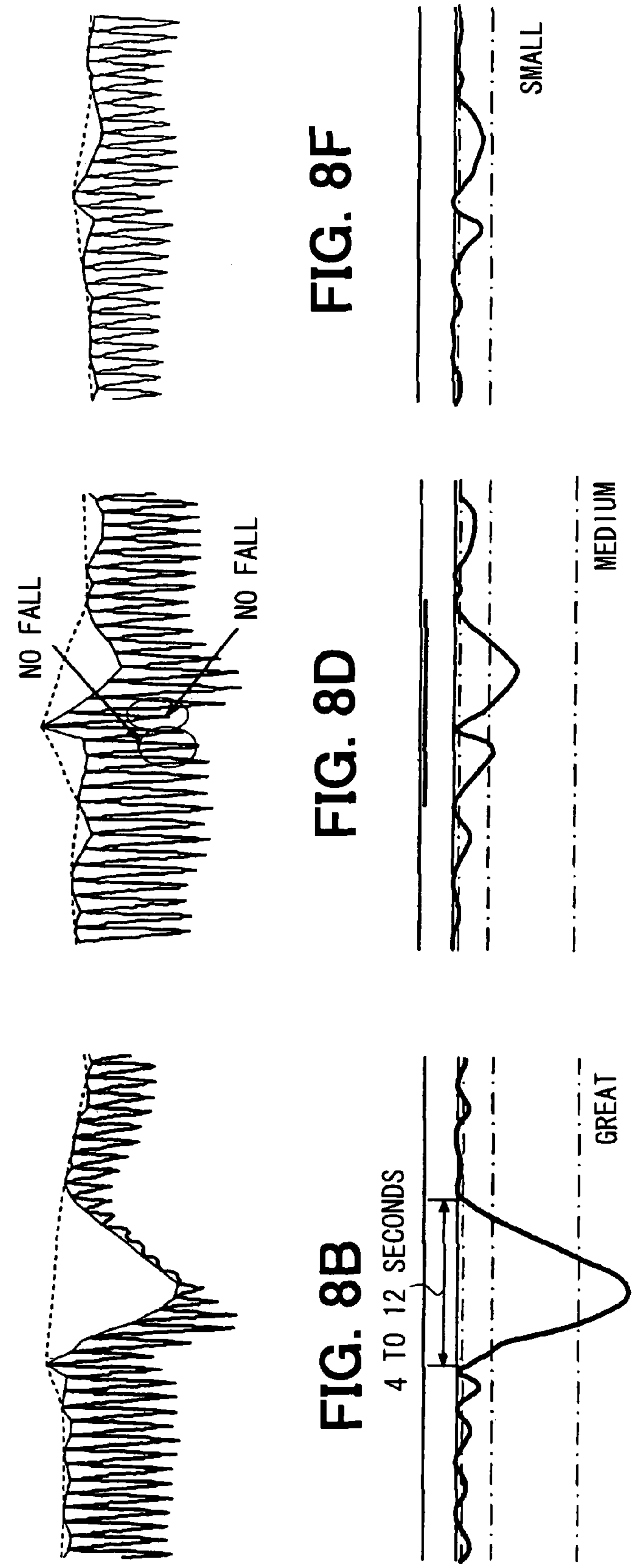


FIG. 8A

FIG. 8B

FIG. 8C

FIG. 8D

FIG. 8E

FIG. 8F

FIG. 9

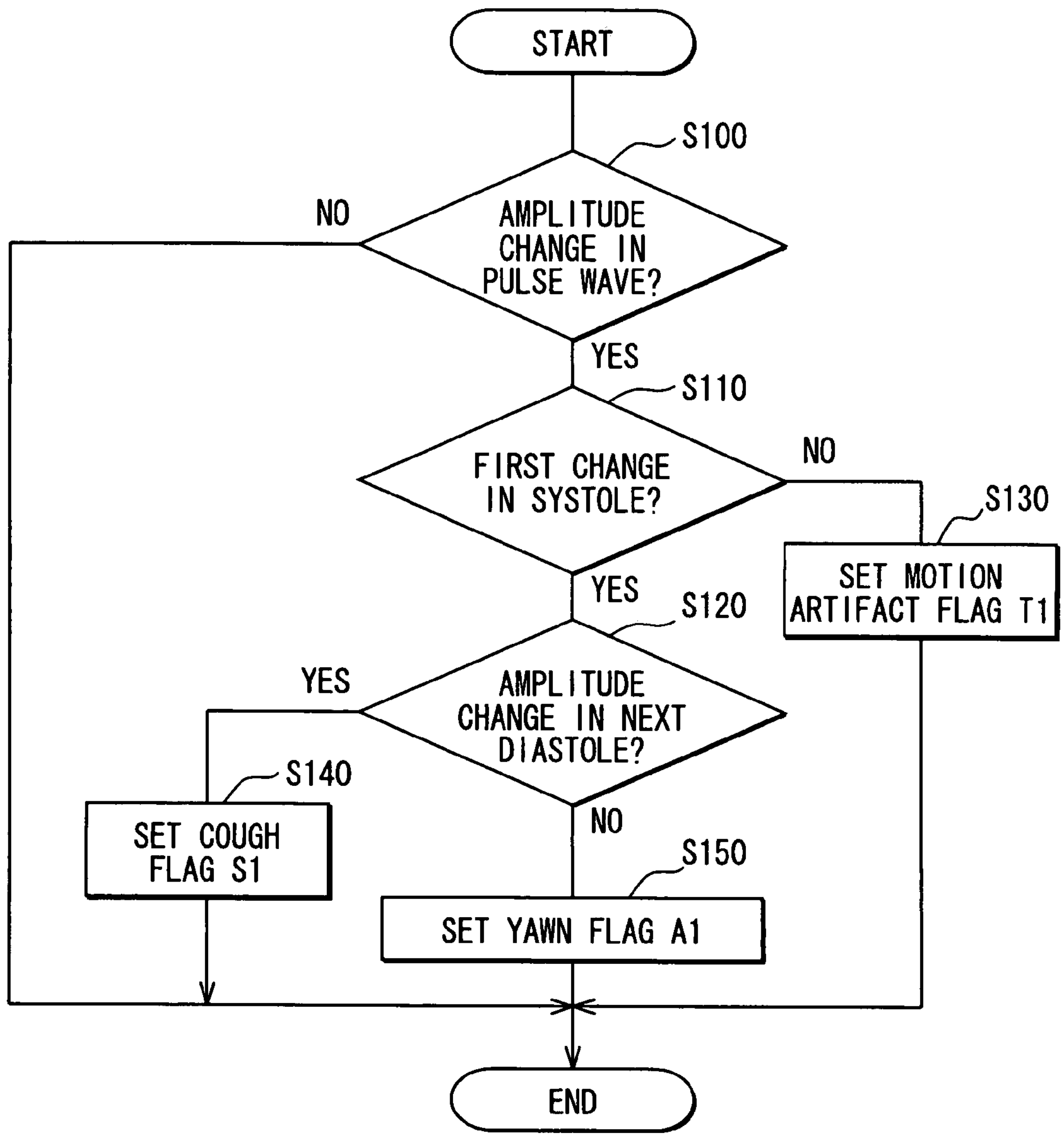

START
S100
AMPLITUDE CHANGE IN PULSE WAVE?
NO
YES
S110
FIRST CHANGE IN SYSTOLE?
NO
S130
SET MOTION ARTIFACT FLAG T1
YES
S120
AMPLITUDE CHANGE IN NEXT DIASTOLE?
YES
S140
SET COUGH FLAG S1
NO
S150
SET YAWN FLAG A1
END

FIG. 10

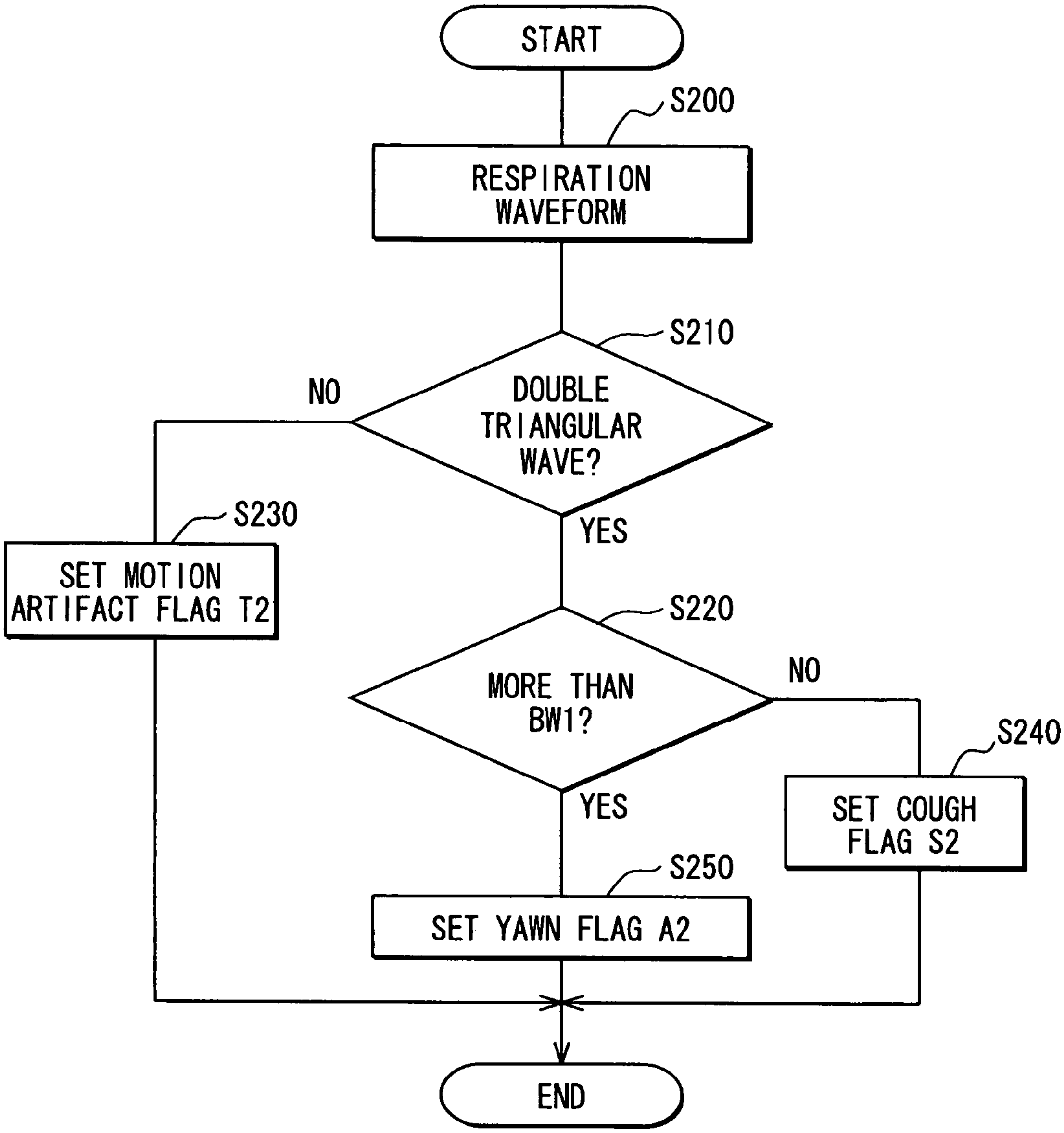

START
S200
RESPIRATION WAVEFORM
S210
DOUBLE TRIANGULAR WAVE?
NO
YES
S230
SET MOTION ARTIFACT FLAG T2
S220
MORE THAN BW1?
NO
YES
S240
SET COUGH FLAG S2
S250
SET YAWN FLAG A2
END

FIG. 11

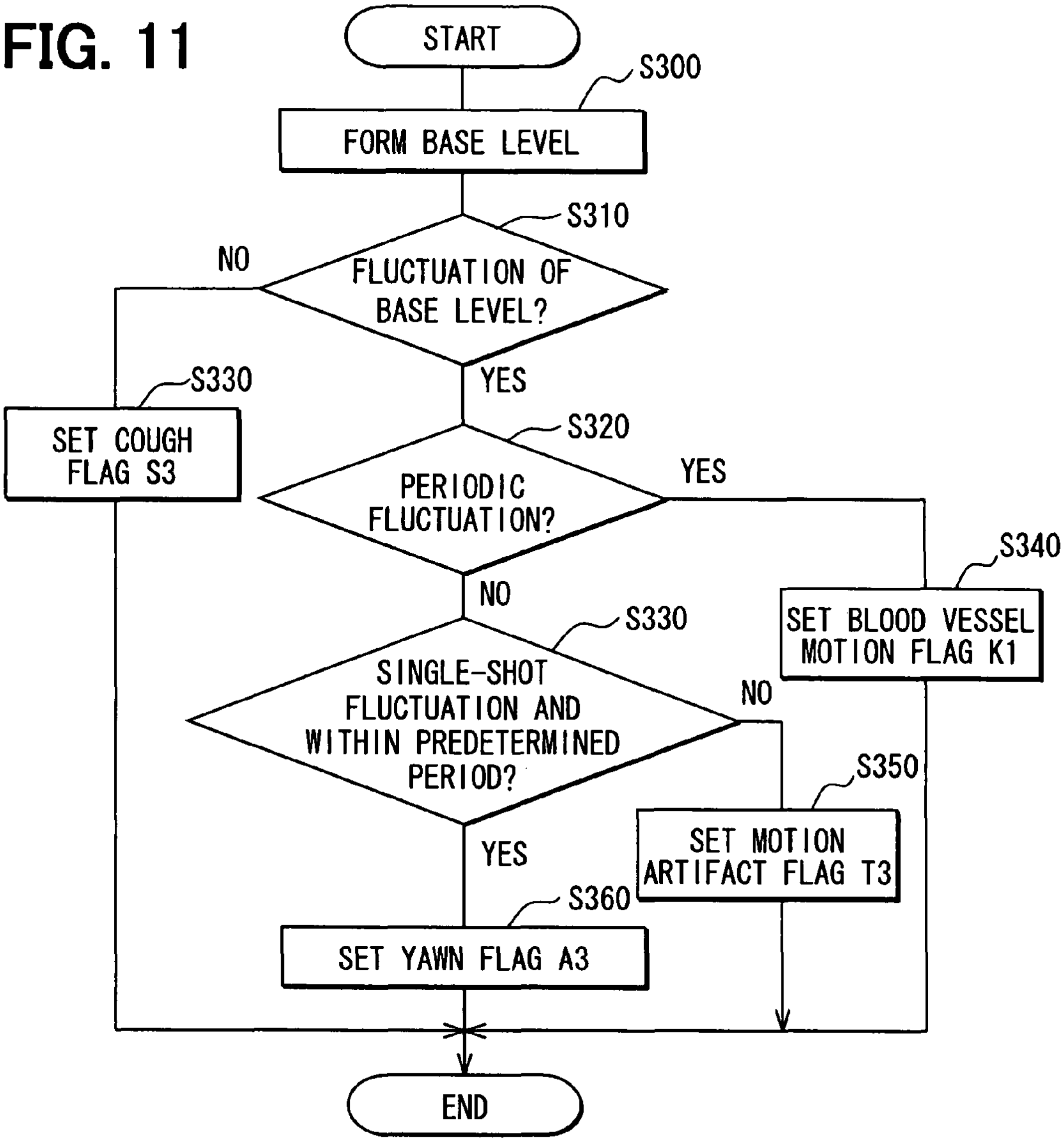
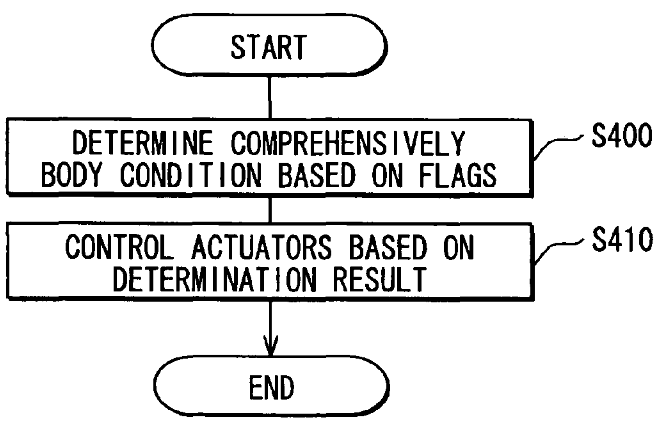

START
S300
FORM BASE LEVEL
S310
FLUCTUATION OF BASE LEVEL?
NO
YES
S330
SET COUGH FLAG S3
S320
PERIODIC FLUCTUATION?
YES
S340
SET BLOOD VESSEL MOTION FLAG K1
NO
S330
SINGLE-SHOT FLUCTUATION AND WITHIN PREDETERMINED PERIOD?
NO
S350
SET MOTION ARTIFACT FLAG T3
YES
S360
SET YAWN FLAG A3
END

FIG. 12


START
DETERMINE COMPREHENSIVELY BODY CONDITION BASED ON FLAGS
S400
CONTROL ACTUATORS BASED ON DETERMINATION RESULT
S410
END

APPARATUS FOR DETECTING VITAL FUNCTIONS, CONTROL UNIT AND PULSE WAVE SENSOR

CROSS REFERENCE TO RELATED APPLICATION

This application is based on and incorporates herein by reference Japanese Patent Application No. 2006-152354 filed on May 31, 2006.

FIELD OF THE INVENTION

This invention relates to a device for detecting vital functions, that is, biometric conditions, such as cough and yawn by using a pulse wave sensor that is easy to mount.

BACKGROUND OF THE INVENTION

A nasal thermistor, a nasal pressure sensor, a chest-band sensor and the like are respiratory system monitors for detecting breathing (respiration), cough and yawn.

As for measuring, for example, the cough, various devices using a spiro-breathing flow meter (patent document 1), signals of the thyroid (patent document 2) and vibration of a catheter (patent document 3). These measuring devices and measuring methods are so complicated that the cough and the like cannot be easily measured in private homes or vehicles.

As simpler technologies, it is proposed to use a pattern of voice signals detected by a microphone (patent document 4) or voice signals and a sound pressure level detected by a microphone (patent document 5). The accuracy of detection is low due to noise, and it is difficult to specify the source of sound when there is a plurality of persons.

It is also proposed to use a camera image of a nose (patent document 6) or variation in a bed load (patent document 7). In case of using the image, the image is taken at a particular position imposing limitation on the position for taking a measurement. Besides, a person puts his or her hand to a mouth when coughing. Therefore, the hand becomes a blind which lowers the accuracy of detection. In case of using the bed load, the motion artifact such as body motion cannot be separated from the cough.

As a method of detecting yawn, further, it is proposed to use a camera image or voice (patent document 8). This method requires a complicated measuring device. It is also proposed to detect respiration conditions by analyzing pulse waves (patent documents 9 to 11).

[Patent document 1] JP-A-8-173403

[Patent document 2] JP-A-9-98964

[Patent document 3] JP-T-11-506380 (U.S. Pat. No. 5,899, 927)

[Patent document 4] JP-A-7-376

[Patent document 5] JP-A-2003-38460

[Patent document 6] JP-A-8-257015 (U.S. Pat. No. 5,704, 367)

[Patent document 7] JP-A-2003-552

[Patent document 8] JP-A-2005-199078

[Patent document 9] JP-A-2002-355227 (U.S. Pat. No. 6,669,632)

[Patent document 10] JP-A-2002-78690 (U.S. Pat. No. 6,856,829)

[Patent document 11] JP-A-2002-153432 (U.S. Pat. No. 6,856,829)

SUMMARY OF THE INVENTION

The present invention has an object of providing an apparatus for detecting vital functions such as cough and yawn

based on a simple method, a control unit therefor and a device for mounting a pulse wave sensor unit.

(1) According to a first aspect of the invention, it is determined that a motion artifact has occurred when the amplitude—during a diastolic phase of a pulse wave ("on p-diastole side" for short)—corresponding to the diastolic phase of the heart has exceeded a predetermined lower-limit level that corresponds to the lowest blood pressure.

Through experiments, it was confirmed that the motion artifact has occurred if the amplitude on p-diastole side falls below the lower-limit level as shown in FIG. **3**A.

Namely, the minimum blood pressure (the diastolic blood pressure) is maintained by the elasticity of blood vessels, and it does not happen that the amplitude on p-diastole side suddenly becomes lower than the lower-limit level as observed based upon the pulse wave signals. If a signal of a pulse wave lower than the diastolic blood pressure appears, therefore, it is regarded that the motion artifact has occurred. In the diagram illustrating the pulse waves, the upper side is expressed to be the side of systole and the lower side is expressed to be the side of diastole for easy comprehension relative to the blood pressure (diagram which is usually called inverted pulse waves).

As the lower-limit level for determining the intensity on p-diastole side, for example, an approximated line can be employed that is found from a plurality of peaks on p-diastole side representing the diastolic blood pressure. However, values that are increased or decreased by a predetermined percentage may be selected as the lower-limit level.

(2) According to a second aspect of the invention, a respiration waveform (respiration curve) that represents the respiration condition is found from the pulse waves. It is determined that a cough has occurred when a double triangular wave of an acute angle is detected, in which two peaks of the respiration waveforms are consecutively exceeding a predetermined level.

If a cough occurs, a double triangular wave of an acute angle lower than a predetermined level (since the thoracic pressure has a negative sign, the respiration waveforms in the graph are expressed protruding downward) is observed within a short period of time (e.g., within 1 to 2 seconds) as shown in FIG. **5**B due to the motion of muscles specific to coughing. Therefore, the above conditions are used for determining the coughing. Here, the double triangular wave of an acute angle has acute angles that are formed by the lines on the outer sides of the right and left peaks.

In case the amplitude of the respiration waveform has increased by more than, for example, 30% beyond the normal amplitude, it is probable that a coughing has occurred. Therefore, there may be added another determining condition, i.e., if the amplitude is greater than a predetermined level. Further, the predetermined level (or the predetermined period) used for the determination can be set by finding an optimum value through experiment (the same holds hereinafter).

(3) According to a third aspect of the invention, it is determined that a cough has occurred when the amplitude—during a systolic phase of a pulse wave ("on p-systole side" for short)—corresponding to the systolic phase of the heart has exceeded a predetermined level (predetermined level on p-systole side) and when the amplitude on p-diastole side corresponding to the succeeding diastolic phase of the heart has exceeded a predetermined level (predetermined level on p-diastole side).

If a cough has occurred, a peak of the pulse wave signal on p-systole side once greatly rises as shown in FIG. **5**A and,

immediately thereafter, the peak on p-diastole side greatly falls. Therefore, this condition is employed as a condition for determining the coughing.

(4) According to a fourth aspect of the invention, it is determined that a cough has occurred when the amplitude on p-systole side corresponding to the systolic phase of the heart has increased by more than a predetermined level (beyond, for example, the normal amplitude on p-systole side) without causing the waveform of the pulse waves to be varied (distorted or broken in shape) from the waveform of ordinary pulse waves.

If the couth has occurred as shown in FIG. **5**A, the amplitude on p-systole side rises without causing the pulse waves to vary. Therefore, this condition is employed as a condition for determining the coughing.

As a method of determining a case where the waveform of the pulse wave varies from the ordinary waveform, there can be employed, for example, a method of obtaining a correlation between the waveforms of pulse waves. For example, waveforms of several pulse waves in an ordinary state free of motion artifact or coughing are averaged to obtain a representative waveform of pulse waves, which is, then, recorded, while a correlation of a waveform of a wavelength or of a plurality of wavelengths is obtained relative to the pulse wave that is to be compared. If the correlation is, for example, not larger than 0.7, it can be so determined that the waveform of the pulse wave has varied. In addition to the correlation, there can be employed the analysis of peak-to-peak pitch variation of the pulse waves or the analysis of chaos.

(5) According to a fifth aspect of the invention, it is determined that a cough has occurred when a change in the ratio (AW**2**/BW**2**) of the amplitude (AW**2**) of the base level of a pulse wave/amplitude (BW**2**) of a pulse wave is within a predetermined level (e.g., a change is within 30% of when there is no motion artifact) and when the time of change is within a predetermined period (e.g., 1 to 2 seconds corresponding to the coughing).

The probability of coughing is high if the above condition is satisfied. Therefore, this condition is employed here as a condition for determining the coughing.

(6) According to a sixth aspect of the invention, it is more reliably determined that a coughing has occurred when a motion artifact is not detected than when the motion artifact is detected while determining the occurrence of coughing based on at least one cough determining method among the above cough determining methods.

The occurrence of coughing and the intensity of coughing can be determined more accurately when a plurality of cough determining methods are used in combination than when the cough determining method of any one of the above aspects is used.

(7) According to a seventh aspect of the invention, it is determined that a yawn has occurred when the base level of a pulse wave is lowered over a predetermined period corresponding to the yawning.

If a yawing has occurred, the base level of pulse waves is mildly lowered as shown in FIG. **7**A due to the motion of muscles specific to the yawning. Therefore, the base level of pulse waves remains lowered for a predetermined period (e.g., 4 to 12 seconds). Therefore, this condition is employed as a condition for determining the yawning.

As a case where the base level is lowered for a predetermined period, there can be employed a period in which the base level is in a lowered state or a period in which the base level is in a state lower than a certain determining value (period of the sum of being lowered and elevated).

(8) According to an eighth aspect of the invention, it is determined that a yawn has occurred when the amplitude of pulse waves has become smaller than a predetermined level (predetermined level for determining the amplitude of pulse waves) within a period in which the base level of pulse waves is lower than a predetermined level (predetermined level for determining the base level).

When the base level of pulse waves has increased from the lowered state as shown in FIG. **7**A, the amplitude of pulse waves (whole amplitude in the up-and-down direction) decreases due to the motion of muscles specific to the yawning. Therefore, this condition is employed as a condition for determination to further improve the accuracy of determination.

(9) According to a ninth aspect of the invention, it is determined that a yawn has occurred when the amplitude on p-systole side corresponding to the systolic phase of the heart exceeds a predetermined level (predetermined level on p-systole side) but the amplitude on p-diastole side corresponding to the diastolic phase of the heart does not become smaller than a predetermined level (predetermined level on p-diastole side).

If a yawn has occurred, a peak on p-systole side slightly increases as shown in FIG. **7**A due to the motion of muscles specific to the yawning. However, a peak of the pulse wave on the side of the expansion period immediately thereafter does not become lower than the normal value (the peak, usually, increases slightly). Therefore, this condition is employed as a condition for determining the yawning.

(10) According to a tenth aspect of the invention, it is determined that a yawn has occurred when the whole amplitude of pulse waves becomes smaller than a predetermined level (predetermined level for determining the whole amplitude) after the amplitude on p-systole side corresponding to the systolic phase of the heart has exceeded a predetermined level (predetermined level for determining the amplitude on p-systole side) without causing the waveform of pulse waves detected by a pulse wave sensor to be varied from the waveform of ordinary pulse waves.

When a yawn occurs as shown in FIG. **7**A, a peak on p-systole side slightly increases and, thereafter, the amplitude of pulse waves decreases without causing the pulse waves to be varied. Therefore, this condition is employed as a condition for determining the yawning.

(11) According to an eleventh aspect of the invention, a respiration waveform representing the respiration state is found from the pulse waves. It is determined that a yawn has occurred when the amplitude of the respiration waveform is not smaller than a predetermined level (predetermined angle for determining the amplitude) and when a double triangular wave of an obtuse angle is detected in which two peaks of the respiration waveform are consecutively exceeding a predetermined level (predetermined level for determining the peak).

If a yawn has occurred as shown in, for example, FIGS. **8**A to **8**C, a double triangular wave of an obtuse angle (of larger than a predetermined amplitude) occurs, in many cases, on the respiration waveform. Therefore, this condition is employed here as a condition for determining the yawning.

Here, the double triangular wave of an obtuse angle stands for a double triangular wave in which the angle formed by lines on the outer sides of the right and left peaks is an obtuse angle.

(12) According to a twelfth aspect of the invention, it is determined that a cough has occurred when a change in the ratio (AW**2**/BW**2**) of the amplitude (AW**2**) of the base level of a pulse wave/amplitude (BW**2**) of a pulse wave is not smaller

than a predetermined level and when the time of change is within a predetermined period corresponding to the yawning.

As shown in FIG. 7, it was clarified that the probability of yawning is high when the change of the ratio (AW2/BW2) is not smaller than a predetermined level and when the time of change is within a predetermined period (e.g., 4 to 12 seconds) corresponding to the yawning. Therefore, this condition is employed here as a condition for determining the yawning.

(13) According to a thirteenth aspect of the invention, it is more reliably determined that a yawn has occurred when a motion artifact is not detected than when the motion artifact is detected while determining the occurrence of the yawn based on at least one yawn determining method among the above yawn determining methods.

The occurrence of yawning and the intensity of yawning can be more accurately determined when a plurality of yawn determining methods are used in combination than when the yawn determining methods of any one of the above aspects is used.

(14) A fourteenth aspect of the invention exemplifies preferred methods for determining the motion artifact.

Described below is another example of methods for determining the motion artifact.

It can be determined that the motion artifact has occurred in case the waveform of the pulse waves has varied from the waveform of the ordinary pulse waves.

That is, in case the motion artifact has occurred, vary of the pulse waves is observed as shown in FIG. 3A. If such a change is detected, therefore, it can be so determined that the motion artifact has occurred. The ordinary pulse waves are pulse waves in a calm state where there is no such changes as motion artifact, cough or yawn.

A respiration waveform (respiration curve) that represents the respiration state is found from the pulse waves. It is so determined that the motion artifact has occurred if the amplitude of the respiration waveform has changed by more than a predetermined level and if the waveform of a pulse wave has varied from the waveform of the ordinary pulse waves.

That is, in case the motion artifact has occurred, a change in the amplitude of the respiration waveform is observed as shown in FIG. 3B in addition to the vary of the waveforms. In case such a change is detected, it may be so determined that the motion artifact has occurred.

Here, as described in the above patent document 9, a first variation signal representing a varying state from the pulse wave is found, a second variation signal representing a varying state of the first variation signal is found, and the respiration waveform (respiration curve) is found based on a difference between the first variation signal and the second variation signal.

As the first variation signal as shown in FIG. 2, there can be employed a first envelope that connects the peaks of waveforms of signals of pulse waves or a first amplitude ratio line that connects the points dividing the amplitudes of waveforms of signals of pulse waves by a predetermined ratio. As the second variation signal, further, there can be employed a second envelope that connects the peaks of waveforms of the first variation signals or a second amplitude ratio line that connects the points dividing the amplitudes of waveforms of the first variation signals by a predetermined ratio.

It can be determined that a motion artifact has occurred when a ratio (AW2/BW2) of the amplitude (AW2) of the base level of a pulse wave/amplitude (BW2) of a pulse wave has changed by more than a predetermined level, the change being of a nature of a single-shot and when the time of change is outside a predetermined period (shorter than, for example, 4 seconds or longer than, for example 12 seconds) that corresponds to the yawning.

Namely, as will be described later, when the ratio (AW2/BW2) of the amplitude (AW2) of the base level of a pulse wave/amplitude (BW2) of a pulse wave has changed by more than a predetermined level, it is probable that a yawning is occurring. However, when the change is of a nature of a single-shot and the period of change is different from the period of the case of yawning, it was clarified through experiments that the probability of motion artifact is high.

Whether the change is of a nature of a single-shot can be determined based on if the change has occurred only once within a preset period (e.g., 20 seconds).

Referring to FIG. 7A, further, the amplitude (AW2) of the base level of the pulse waves stands for a width of deviation from the center of the base level while the amplitude (BW2) of the pulse waves represents the whole width in the up-and-down direction of the pulse waves. As the amplitude of the base level of the pulse waves, however, there can be employed the hole amplitude in the up-and-down direction of the base level.

When it is determined by a plurality of motion artifact-determining method that a motion artifact has occurred, it can be more reliably determined that the motion artifact has occurred than when it is not.

That is, the accuracy of determination can be more improved when a plurality of motion artifact determinations are combined together than when each of the above motion artifact determinations is used.

As described above in detail, the apparatus for detecting the conditions of a body of the second to fourteenth aspects detects the cough or yawn by utilizing signals obtained through a pulse wave sensor, i.e., easily detects the cough or yawn (or deep respiration) in private homes or vehicle compartments based on a method simpler than the conventional methods.

In the above aspects, the pulse waves can be measured from an arm or a finger in addition to the face by using the pulse wave sensor offering a distinguished effect of cleanly taking a monitoring at a portion kept away from the cough, spit or phlegm that could become a cause of infectious disease to the respiratory systems.

On account of each time of cough or yawn can be detected, it is allowed to find the number of coughs and yawns (to render a quantitative evaluation). Based on the number theory, therefore, it is also allowed to diagnose the degree of symptom such diseases as chronic bronchitis or whooping cough, or to detect the sign of sleepiness.

(15) According to a fifteenth aspect of the invention, when the occurrence of cough or yawn is determined by the above various methods for determining the cough or yawn (inclusive of definite cough determining method definite yawn determining method), various actuators are controlled such as adjusting the temperature and blow rate of an air conditioner, offering a guide by the navigation system or varying the state of the seat and the seat belt based upon the results of determination, for example, upon the symptoms so as to relax the coughing or to promote the recovery from the sleepiness.

That is, an alarm is produced as required, or the environment is controlled being linked to the air conditioner. Further, the disease is determined based on the determined results of coughing and yawning. If it is a cold, the temperature and humidity are suitably set. If it is an allergic rhinitis, the air in the compartment may be replaced with the fresh external air or an auxiliary filter may be operated. Further, the data of the

determined results may be stored to be used for controlling the health and for the diagnosis by a doctor.

(16) In a sixteenth aspect of the invention, further, if a pulse wave sensor is of an optical type, a buffer member is arranged between the pulse wave sensor and the skin so that the optical device of the skin side does not come in contact with the skin or pushes the skin with a pressure which is not larger than a predetermined level.

This restricts the pulse wave sensor from pushing the skin with an excess of pressure, and the blood circulation is not restricted. Therefore, the measurement can be taken accurately.

(17) According to a seventeenth aspect of the invention, a sponge having a rugged pattern on the skin side may be used as the preferred buffer member.

(18) In an eighteenth aspect of the invention, if the pulse wave sensor is of the optical type, an elastic member may be arranged on the pulse wave sensor on the side opposite to the skin for mounting the pulse wave sensor on the surface of the body, so that the optical device pushes the skin with a pressure which is not larger than a predetermined level.

This prevents the pulse wave sensor from pushing the skin with an excess of pressure. Therefore, an excess of load is not given to the skin, the waveforms of pulses are not distorted, and the pulse waves can be accurately measured.

(19) A nineteenth aspect of the invention uses a band (for example, a rubber material or an expansible bandage) as a preferred elastic member for fixing the pulse wave sensor to the body.

(20) A twentieth aspect of the invention uses a member (for example, a spring or the like) as a preferred elastic member for fixing the pulse wave sensor to the body.

BRIEF DESCRIPTION OF THE DRAWINGS

The above and other objects, features and advantages of the present invention will become more apparent from the following detailed description made with reference to the accompanying drawings. In the drawings:

FIG. **1**A is a schematic diagram illustrating an apparatus for detecting the conditions of a body and a mounting device therefor according to an embodiment, and FIG. **1**B is an enlarged schematic view illustrating a pulse wave sensor used in the embodiment;

FIG. **2**A is a graph illustrating a waveform of pulse waves, and FIG. **2**B is a graph illustrating a respiration waveform;

FIG. **3**A is a graph illustrating a waveform of pulse waves of when there is a motion artifact, and FIG. **3**B is a graph illustrating a respiration waveform of when there is a motion artifact;

FIG. **4**A is a graph illustrating a waveform of pulse waves of when there is a strong motion artifact, FIG. **4**B is a graph illustrating a respiration waveform of when there is a strong motion artifact, FIG. **4**C is a graph illustrating a waveform of pulse waves of when there is a motion artifact of an intermediate degree, FIG. **4**D is a graph illustrating a respiration waveform of when there is a motion artifact of an intermediate degree, FIG. **4**E is a graph illustrating a waveform of pulse waves of when there is a weak motion artifact, and FIG. **4**F is a graph illustrating a respiration waveform of when there is a weak motion artifact;

FIG. **5**A is a graph illustrating a waveform of pulse waves of when a cough has occurred, and FIG. **5**B is a graph illustrating a respiration waveform of when a cough has occurred;

FIG. **6**A is a graph illustrating a waveform of pulse waves of when a strong cough has occurred, FIG. **6**B is a graph illustrating a respiration waveform of when a strong cough has occurred, FIG. **6**C is a graph illustrating a waveform of pulse waves of when a cough of an intermediate degree has occurred, FIG. **6**D is a graph illustrating a respiration waveform of when a cough of an intermediate degree has occurred, FIG. **6**E is a graph illustrating a waveform of pulse waves of when a weak cough has occurred, and FIG. **6**F is a graph illustrating a respiration waveform of when a weak cough has occurred;

FIG. **7**A is a graph illustrating a waveform of pulse waves of when a yawn has occurred, and FIG. **7**B is a graph illustrating a respiration waveform of when a yawn has occurred;

FIG. **8**A is a graph illustrating a waveform of pulse waves of when a strong yawn has occurred, FIG. **8**B is a graph illustrating a respiration waveform of when a strong yawn has occurred, FIG. **8**C is a graph illustrating a waveform of pulse waves of when a yawn of an intermediate degree has occurred, FIG. **8**D is a graph illustrating a respiration waveform of when a yawn of an intermediate degree has occurred, FIG. **8**E is a graph illustrating a waveform of pulse waves of when a weak yawn has occurred, and FIG. **8**F is a graph illustrating a respiration waveform of when a weak yawn has occurred;

FIG. **9** is a flowchart illustrating processing for setting flags T**1**, S**1** and A**1**;

FIG. **10** is a flowchart illustrating processing for setting flags T**2**, S**2** and A**2**;

FIG. **11** is a flowchart illustrating processing for setting flags T**3**, S**3** and A**3**; and

FIG. **12** is a flowchart illustrating control processing based on a comprehensive determination of the motion artifact, coughing and yawning.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

First, a biometric detection apparatus for detecting conditions of a body is described with reference to one embodiment shown in FIGS. **1**A and **1**B. The apparatus detects vital functions such as cough or yawn by using a pulse wave sensor **1**. This sensor **1** is attached to a portion of a human body **100** such as a finger, a palm or a wrist, where motion is small. The apparatus further uses a control unit **3**, which drives the pulse wave sensor **1** and processes the outputs from the pulse wave sensor **1**.

Here, the pulse wave sensor **1** is an optical sensor of the reflection type (opto-capacitive pulse wave sensor) comprising a light-emitting element (e.g., light-emitting diode: green LED) **5**, a light-receiving element (e.g., photodiode: PD) **7**, and a transparent lens **9** which permits light to pass through and also efficiently receives light.

The pulse wave sensor **1** has a ring-like buffer member (e.g., a sponge having a rugged end) **11** that serves as a spacer surrounding the lens **9** on the skin side so that the lens **9** will not be pushed onto the skin **100***a* with an excess of pressure, and a spring **13** on the rear end side of the pulse wave sensor **1**. This makes it possible to set the pressure for pushing the lens **9** onto the skin **100***a* to be not larger than 10 gw/cm^2. The pulse wave sensor **1** is fixed to the wrist or the like by using a band **15**. Therefore, the spring **13** is arranged between the band **15** and the pulse wave sensor **1**.

When the pulse wave sensor **1** is to be used, a driving electric power is supplied from a drive unit **17** in the control unit **3** and light is projected to the human body from the light-emitting element **5**. Part of the light hits capillary vessels (capillary arteries) in the human body, is absorbed mostly by hemoglobin in the blood flowing through the capillary vessels, while rest of the light scatters repetitively and partly

falls on the light-receiving element **7**. Due to the pulsation of blood at this moment, the amount of hemoglobin in the capillary vessels vary periodically like a wave and, therefore, the light absorbed by the hemoglobin varies like a wave, too.

As a result, the amount of light absorbed by the capillary vessels varies and, accordingly, the amount of light received or detected by the light-receiving element **7** varies. A change in the amount of the received light is output as pulse wave data (sensor output which is a voltage signal representing the pulse wave) to the control unit **3**.

The control unit **3** includes the drive unit **17**, a detector unit **19** that receives a sensor output, a microcomputer **21** which produces a control signal to the drive unit **17** and to an output unit **23** and receives signals from the detector unit **19** and from an input unit **25** to execute various processing, the output unit **23** that sends control signals to various actuators **27**, and the input unit **25** that receives a signal from a manual switch **29**.

The microcomputer **21** is an electronic circuit including known CPU, ROM, RAM and the like, and incorporates a program for detecting the coughing and yawning by processing pulse wave signals applied from the pulse wave sensor **1**.

The pulse wave sensor **1** may be attached to any part of the body but is desirably attached to an arm, hand, finger, forehead or foot that is less affected by the motion artifact.

Next, the principle for detecting the coughing and yawning will be described with reference to FIGS. **2**A to **8**F. In these figures, the abscissa represents the passage of time and the ordinate represents the magnitude (intensity or variation) of the signals.

Referring first to FIG. **2**A, the pulse wave sensor **1** produces pulse wave signals having peaks corresponding to the systolic phase and to the diastolic phase of the heart. Specifically, varying peaks appear in the upper side in the figure during the systolic phase of the heart, and varying peaks appear in the lower side in the figure during the diastolic phase of the heart.

During the ordinary calm state, i.e., when there is no motion artifact, cough or yawn, and there is only a very mild variation of a large period due to the motion of the blood vessels, variation of the blood pressure in the blood vessels is slow. As a result, the peaks of signals on p-diastole side do not become lower than a predetermined low-limit level LL (line corresponding to the lowest blood pressure).

As a method of setting the lower-limit level LL, there can be exemplified an approximated line found, for example, from a plurality of peaks on p-diastole side representing the lowest blood pressure.

A line connecting the centers of the upper and lower peaks of pulse wave signals is called the base level BL (index related to an average blood pressure). Further, a line connecting the peaks of signals on p-systole is called a pulse wave envelope (first envelope) A, and a line connecting the peaks of the first envelope is called a double envelope (second envelope) B. Referring to FIG. **2**B, a waveform found by subtracting the second envelope B from the first envelope A is called a respiration waveform (respiration curve). The respiration waveform is a signal corresponding to the intra-thoracic pressure.

The principle of the processing of the embodiment conducted by using the above signals is described next.

(1) Method of Detecting Motion Artifact

Referring to FIG. **3**A, when a motion artifact has occurred, the pulse wave on p-diastole side, first, so varies as to becomes lower than (fall below) the lower-limit level LL from the ordinary (calm) pulse waves, i.e., from the state of the regular sinusoidal pulse wave signals. The frequency of pulse wave signals of this period becomes smaller than the frequency of the ordinary pulse wave signals (of when there is no

motion artifact) (e.g., state of high-frequency noise) and the waveforms, in many cases, greatly vary from the sinusoidal waves.

If the signal on p-diastole side exceeds the lower-limit level LL, therefore, it can be so determined that the motion artifact has occurred. Here, if the waveform varies or the frequency of pulse wave signals becomes small, it is highly probable that the motion artifact has occurred.

Referring to FIGS. **4**B, **4**D and **4**F, further, the respiration waveform found from the peaks on p-systole differs depending upon the intensity (strength) of the motion artifact. Therefore, the intensity of motion artifact can be determined from the state of the respiration waveform. If the motion artifact is great, for example, the respiration waveform falls greatly and a curve thereof becomes sharp as shown in FIG. **4**B. If the motion artifact is medium, the respiration waveform falls greatly but a curve thereof becomes loose. If the motion artifact is small, the respiration waveform falls little.

Accordingly, the motion artifact can be accurately detected by each of the following determining methods (algorithms) or by a combination of the determining methods. The following determining methods have all been confirmed through the practically conducted experiments (the same also holds for the coughing and yawning).

In case the amplitude on p-diastole side has increased (i.e., in case the peaks of amplitude on p-diastole side have exceeded a predetermined level or have become smaller than the lower-limit level LL, it is determined that the motion artifact has occurred (motion artifact flag T**1** is set as described later).

In case the waveform of pulse waves has varied from the sinusoidal wave, it is determined that the motion artifact has occurred. Whether the waveform has varied from the sinusoidal waves can be determined based on a correlation to the waveform of the ordinary (e.g., preceding) pulse wave. For example, it can be regarded that the waveform has varied if a coefficient of the correlation is not larger than 0.7.

In case the amplitude of the respiration waveform has varied and the waveform of pulse waves has varied from the sinusoidal waves, it can be determined that the motion artifact has occurred. Here, if the waveform has varied from the sinusoidal waves can be determined based on a correlation to the waveform of the ordinary pulse waves (for example, it can be regarded that the waveform has varied if a coefficient of the correlation is not larger than 0.6).

In case there is a change in the amplitude AW**2** of the base level BL divided by the amplitude BW**2** of pulse waves (FIG. **7**), the change is a nature of a single-shot and the time of change is as short as 0 to 4 seconds or as long as 12 seconds or more, it is determined that the motion artifact has occurred (motion artifact flag T**3** is set as described later).

A change from the sinusoidal waves or a change in the amplitude can be determined from the analysis of variation in the peak-to-peak pitch or from the analysis of chaos in addition to utilizing the correlation (the same holds hereinafter).

(2) Method of Detecting Cough

Referring to FIG. **5**A, if the cough has occurred, the amount of terminal blood temporarily increases due to instantaneous contraction of muscles accompanying the coughing. The pulse wave on p-systole side, first, increases greatly from the state of ordinary pulse wave signals.

The coronary veins are compressed by the abdominal muscles that have tensed due to coughing, the blood returning to the heart instantaneously decreases. The heart blows out the blood in decreased amounts. Accordingly, the pulse wave on p-systole side immediately after the rise falls greatly in excess of the lower-limit level. The time of coughing is so

short that there is no change in the amplitude of the pulse wave signals, and the base level readily restores. In the case of the coughing, usually, no change is seen in the frequency and there is almost no change in the shape of the sinusoidal waves, either.

In case the cough occurs, further, a double waveform (double triangular wave) of a characteristic acute angle appears on the respiration waveform obtained from the pulse waves as shown in FIG. **5**B. A large ratio (AW**1**/BW**1**) of the longitudinal width (amplitude) AW**1** and the transverse width (period) BW**1** of the double triangular wave represents an intense coughing in which the intrathoracic pressure sharply changes within a short period of time.

What makes the double triangular wave may be determined relying, for example, upon "if the determining line is exceeded that is separated away from the ordinary line of the respiration waveform by more than a predetermined percentage".

Therefore, if the pulse wave on p-systole side, first, greatly increases (in excess of the predetermined upper-limit level) and, immediately thereafter, the pulse wave on p-diastole side exceeds the lower-limit level, it can be determined that the cough has occurred. Further, if the double triangular wave appears on the respiration waveform, it can be determined that the cough has occurred.

Referring to FIGS. **6**A to **6**F, further, the pulse wave signal and the respiration waveform differ depending upon the intensity of coughing. From the states thereof, therefore, the intensity of coughing can be checked if the coughing is intense, for example, the pulse wave signals vary greatly in the up-and-down direction as shown in FIG. **6**A, the respiration waveform falls greatly as shown in FIG. **6**B, and the ratio AW**1**/BW**1** becomes large. If the coughing is of the medium degree, further, the pulse wave signals vary up and down to a slightly large extent as shown in FIG. **6**C, the respiration waveform falls to a medium degree as shown in FIG. **6**D, and the ratio AW**1**/BW**1** is of a medium degree. Further, if the coughing is weak, the pulse wave signals vary up and down to a small degree, and the respiration waveform falls mildly.

Thus, the coughing can be accurately detected by the combination of one or two or more kinds of the following determining methods.

If the amplitude on p-systole side increases (i.e., if the peak of amplitude increases on p-systole side) and the amplitude on p-diastole side increases (i.e., if the peak of amplitude is lowered on p-diastole side), it is determined that the coughing has occurred (cough flag S**1** is set as described later).

If the amplitude on p-systole side increases (i.e., if the peaks increase on p-systole side only) without causing the waveform of pulse waves to be varied from the sinusoidal waves, it can be regarded that the cough has occurred.

If the amplitude of the respiration waveform varies (increases by 30% above the normal value) and a double waveform of an acute angle appears on the respiration waveform, it is determined that the coughing has occurred (cough flag S**2** is set as described later).

If (amplitude AW**2** of the base level/amplitude BW**2** of the pulse waves) of pulse waves varies little (decreased by 30% below the normal) and the time of change is shorter than a predetermined level (e.g., shorter than 4 seconds), it is determined that the cough has occurred.

Here, it is important that in detecting the coughing, the motion artifact is determined, too. Even in case it is determined that the cough has occurred by the above determining method, it is determined that the cough has occurred only when it is so determined that there is no motion artifact. This is to isolate the motion artifact from the cough to render an accurate determination.

(3) Method of Detecting Yawn (Deep Respiration)

Referring to FIG. **7**A, if the yawn (or deep respiration) has occurred, the amount of terminal blood temporarily increases to some extent due to mild contraction of muscles accompanying the yawn. Therefore, the systolic pulse wave, first, increases to some extent from the ordinary state of pulse wave signals.

Thereafter, the coronary veins are compressed by the abdominal muscles that have tensed due to coughing, the blood returning to the heart gradually decreases. Therefore, the heart blows out the blood in decreased amounts for several seconds. Accordingly, the base level of the pulse wave signals gradually decreases. At this moment, the base level gradually decreases as designated at AW**2** in proportion to the intensity of yawning, and the amplitude BW**2** of the pulse waves decreases.

The reflux of blood to the heart is squeezed for several seconds due to the yawning, and about 10 seconds are needed before the pulse wave is recovered. In the case of the yawning, the sinusoidal waves of pulse wave signals do not change much, and a double triangle of an obtuse angle having a wide bottom side is seen on the respiration waveform.

It can be determined that the yawn has occurred based on a decrease in the base level of pulse wave signals, on a decrease in the respiration waveform (e.g., based on a decreased state lasting for 4 to 12 seconds) or on a decrease in the amplitude of pulse waves.

Referring to FIGS. **8**A to **8**F, further, the pulse wave signal and the respiration waveform differ depending upon the intensity of yawning. From the states thereof, therefore, the intensity of yawning can be checked if the yawning is intense, for example, the pulse wave signals and the respiration waveform fall greatly as shown in FIGS. **8**A and **8**B. Besides, the width of fall is great (4 to 12 seconds) and the amplitude of pulse wave signals becomes considerably small after the fall as shown in FIG. **8**A. If the yawning is of the intermediate degree, further, the pulse wave signals and the respiration signals fall to a medium degree as shown in FIGS. **8**C and **8**D. Besides, the width of fall is of a medium degree and the amplitude of the pulse wave signals does not change much as shown in FIG. **8**C. Further, if the yawning is weak, the pulse wave signals and respiration signals fall little or the width of fall is small as shown in FIGS. **8**E and **8**F, and the amplitude of the pulse wave signals does not change much as shown in FIG. **8**E.

Therefore, the yawning can be accurately detected by the combination of one or two or more kinds of the determining methods.

If the waveform on p-systole increases (i.e., if the peak of pulse waves during systole increases) but the peak of pulse waves on the side of the next diastole does not become smaller than that of the ordinary case, it is determined that the yawn has occurred (yawn flag A**1** is set as described later).

If the amplitude on p-systole side increases and, thereafter, if the whole amplitude BW**2** of pulse waves decreases without causing the waveform of pulse waves to vary from the sinusoidal waves, it is determined that the yarn has occurred.

If the amplitude of the respiration waveform varies and a double curve of an obtuse angle appears on the respiration waveform, it is determined that the yawn has occurred (yawn flag A**2** is set as described later).

If the ratio AW**2**/BW**2** (amplitude AW**2** of the base level divided by amplitude BW**2** of the pulse waves) of pulse waves varies greatly (larger by 30% or more above the normal) and

the time of change is longer than a predetermined value (e.g., longer than 8 seconds), it is determined that the yawn has occurred.

It is important that in detecting the yawn, the motion artifact is determined, too. Even in case it is determined that the yawn has occurred by the above determining method, it is determined that the yawn has occurred only when it is so determined that there is no motion artifact. This is to separate the motion artifact from the yawning to render an accurate determination.

Next, processing executed by the control unit **3** based on the above principles will be described with reference to flowcharts of FIGS. **9** to **12**.

These processing employs some of the above determining methods to finally determine the occurrence of the motion artifact, coughing and yawning.

(I) Referring to FIG. **9**, it is checked at step (S) **100** if there is a change in the amplitude of pulse wave signals produced by the pulse wave sensor **1**. Specifically, it is checked if the amplitude of pulse wave signals is varying up and down by not less than 30% beyond the up-and-down amplitude of the ordinary pulse wave signals, or if the amplitude on p-systole side (or the amplitude on p-diastole side) is varying by not less than 30% beyond the amplitude of the ordinary pulse wave signals on p-systole side (or beyond the amplitude on p-diastole side). If the determination is affirmative, the routine proceeds to step **110**. If the determination is negative, the processing once ends.

That is, if the amplitude exceeds by more than 30% beyond the amplitude of the ordinary pulse wave signals, it can be presumed that motion artifact, coughing, yawning or the like, which is different from the ordinary calm state, has occurred.

At step **110**, it is checked if a large change in the amplitude detected at step **100** is on p-systole side. If the determination is affirmative, the routine proceeds to step **120**, if the determination is negative, the routine proceeds to step **130**.

When a first large change in the amplitude (peak protruding downward) is on p-diastole side, it is highly probable that the motion artifact has occurred as shown in FIG. **3**A. Therefore, at step **130**, a motion artifact flag T**1** is set to represent the above fact, and the processing once ends.

If the first large change in the amplitude is on p-systole side, the probability of motion artifact is low. It is, therefore, probable that the cough or the yawn has occurred. It is checked at step **120** if the amplitude in the next diastole is varying by more than 30%. If the determination is affirmative, the routine proceeds to step **140**. If the determination is negative, the routine proceeds to step **150**.

If the amplitude in the next diastole is varying by more than 30%, as shown in FIG. **5**A, it can be presumed that the cough has occurred highly probably. That is, the pulse wave signals are, first, greatly varying on p-systole side and, immediately thereafter, are greatly varying on p-diastole side. Thus, it is presumed that the probability of cough is high. A cough flag S**1** is set at step **140** to represent the above fact, and the processing once ends.

If neither the motion artifact nor the cough is occurring, based on the elimination method, it is presumed that the above variation in the pulse wave signals at step **100** above is caused by the yawning. Therefore, a yawn flag A**1** is set at step **150** to represent the above fact, and the processing once ends.

If there is a large change in the pulse wave signals, the flag of any one of the motion artifact, coughing or yawning can be set based on the state where the pulse wave signals are varying.

(II) Referring to a flowchart of FIG. **10**, a respiration waveform (respiration curve) is generated or formed at step **200** based on the pulse wave signals produced from the pulse wave sensor **1**.

At subsequent step **210**, it is checked if there is a double triangular wave on the respiration curve. Specifically, it is checked if there is a W-shaped waveform (waveform having a protrusion on the upper side) under the predetermined determining level of the respiration curve as shown in FIG. **5**B. If the determination is affirmative, the routine proceeds to step **220**. If the determination is negative, the routine proceeds to step **230**.

If there is no double triangular wave, it is presumed that there is the motion artifact and the motion artifact flag T**2** is set at step **230** to once end the processing.

At step **220**, it is checked if the double triangular wave is a double triangular wave of an obtuse angle of more than a predetermined time width BW**1** (e.g., 4 seconds at the predetermined determining level PDL). Namely, it is checked here if the double triangular wave has an obtuse angle by checking the predetermined width BW**1**. If the determination is affirmative, the routine proceeds to step **250**. If the determination is negative, the routine proceeds to step **240**.

Here, the addition of a condition "a change in the amplitude of the pulse wave curve is greater than the normal value by more than 30%" further improves the accuracy of determination.

If the double triangular wave has an acute angle as shown in FIG. **5**B, it is highly probable that the cough has occurred. Therefore, a cough flag S**2** is set at step **240** to represent the above fact, and the processing once ends.

If the double triangular wave is not of an acute angle, it is highly probable that the yawn has occurred instead of the cough (without motion artifact). Therefore, a yawn flag A**2** is set at step **250** to represent the above fact, and the processing once ends.

If there is a large change in the respiration curve, a flag of any one of the motion artifact, coughing or yawning is set based on the state of change in the respiration curve.

(III) Referring to a flowchart of FIG. **11**, a base level (line) BL is formed based on the pulse wave signals produced from the pulse wave sensor **1**.

At subsequent step **310**, it is checked if the base level of the pulse waves is fluctuating. Specifically, as shown in FIG. **7**A, it is checked if ration AW**2**/BW**2** (amplitude AW**2** of the base level (herein, amplitude from an average value of the base level in normal operation) divided by amplitude BW**2** of each pulse wave signal) is greater than a predetermined determining value (e.g., if the change is greater than the normal value by more than 30%). If the determination is affirmative, the routine proceeds to step **320**. If the determination is negative, the routine proceeds to step **330**.

If there is no fluctuation in the base level BL, a cough flag S**3** is set at step **330** presuming that the cough has occurred, and the processing once ends.

It is checked at step **320** if the base level is fluctuating periodically (at a period of, for example, 6 to 15 seconds). If the determination is affirmative, the routine proceeds to step **340**. If the determination is negative, the routine proceeds to step **330**.

If the period of fluctuation of the base level is long, it is so determined that the fluctuation is arising from the motion of blood vessels. A blood vessel motion flag K**1** is set at step **340** to represent the above fact, and the processing once ends.

At step **330** it is checked if the fluctuation of the base level is of a nature of a single-shot and is within a predetermined period (e.g., 4 to 12 seconds). If the determination is affirma-

tive, the routine proceeds to step **360**. If the determination is negative, the routine proceeds to step **350**.

If the fluctuation of the base level is of the nature of a single-shot and is within the predetermined period (e.g., 4 to 12 seconds) as shown in FIG. **7**B, it can be presumed that the yawn has occurred. Therefore, a yawn flag A**3** is set at step **360**, and the processing once ends.

If the fluctuation is not a single-shot or more than the predetermined period, a motion artifact flag T**3** is set at step **350** presuming that the motion artifact may have occurred, and the processing once ends.

The fluctuation of the base level is thus analyzed, and the flag of any one of the motion artifact, coughing or yawning is set.

(IV) Referring to a flowchart of FIG. **12**, vital function, such as respiration and pulsation is comprehensively determined based on the flags.

For example, when three kinds of motion artifact flags T**1** to T**3** are set, it can be reliably determined that the motion artifact has occurred. Further, when one or two flags are set among the three kinds of motion artifact flags T**1** to T**3**, it may be so determined that the motion artifact has occurred. The reliability of motion artifact increases with an increase in the kinds of the flags that are set. Among the three kinds of motion artifact flags T**1** to T**3**, there is a flag which highly represents the motion artifact (e.g., motion artifact flag T**1**). If this flag is set, it may be so determined that the motion artifact has occurred. Alternatively, a large threshold value may be set to the counter for the motion artifact flag that represents a high probability. The motion artifact may be determined based on a total value of the motion artifact flags counted by the counter.

What is described above holds even for the three kinds of cough flags S**1** to S**3** and yarn flags A**1** to A**3**. If the cough flag S**1** is set, it is most probable that the cough has occurred. If the yawn flag A**3** is set, it is most probable that the yawn has occurred.

Even if it is determined that the cough or the yawn has occurred based on the cough flags S**1** to S**3** or the yawn flags A**1** to A**3**, it may be often determined that the motion artifact has occurred based on the motion artifact flags T**1** to T**3**. In such a case, it is not determined that the cough or the yawn has occurred but, instead, it is determined that the motion artifact has occurred, reducing erroneous determination.

At next step **410**, actuators are controlled, such as the air conditioner, navigation system, seats, seatbelts, etc. based on the above determined results, and the processing once ends.

The following processing can be employed for controlling the actuator.

For example, disorders of respiration such as asthma and emphysema of the lungs, disorders of inspiration such as rhinitis and nasal congestion, and cold can be presumed from the frequency and intensity of coughing, number of beats, number of breaths, a curve of respiration and fluctuation in the respiration (respiration signals). The air conditioner, air cleaner, navigation system, audio equipment, seats and seat belts are adjusted depending upon the symptoms that are presumed.

Specifically, the following control operations may be executed, for example.

If the cough is detected while an alarm of ear pollen has been issued, the conditioned air in the compartment is switched to the air-recirculation mode (internal circulation mode), and an auxiliary filter such as an air-purifier is operated. If the coughing occurs more frequently than usual, it is so presumed that the person is having a slight cold, the compartment temperature and the humidity are set to be slightly higher. Further, if the yawn is frequently detected, information is produced from the navigation system to stimulate the driver's brain to prevent him from becoming sleepy. If the yawn still occurs too frequently, the tension of the seat belt is varied to stimulate the body to keep the person awake.

In addition to the above results of presumption, other pulse wave data (pulse waveform, fluctuation in the pulse wave amplitude, pulse rate, variation in the interval between pulses, etc.) may be added or any other body data signals (blood pressure, electrocardiograph, electromyograph, camera image) may be added to presume the condition of the body at that moment to correct the control of air-conditioner, air-purifier, navigation system, audio equipment, seats and seat-belts.

The present invention is not limited to the above embodiments only but can be put into practice in a variety of other ways.

What is claimed is:

1. An apparatus for detecting vital functions, comprising:

sensing means adapted for attachment to a body and produces pulse wave signals corresponding to pulse waves of the body; and

respiration waveform calculation means for finding a respiration waveform that represents a respiration condition from the pulse waves detected by the sensing means; and

cough determining means which determines an occurrence of a cough when formation of a double triangular wave is detected, the double triangular wave having an acute angle in which two peaks of the respiration waveform consecutively exceed a predetermined level.

2. An apparatus for detecting vital functions according to claim **1**, further comprising:

motion artifact determining means which determines an occurrence of a motion artifact based on the pulse waves detected by the sensing means, wherein

the cough determining means determines the occurrence of the cough when the motion artifact determining means additionally determine no occurrence of the motion artifact.

3. The apparatus according to claim **1**, wherein the sensing means includes:

an optical device for projecting light onto a skin of the body to measure the pulse waves of the body; and

a buffer member arranged between the optical device and the skin so that the optical device of the skin side does not come in contact with the skin or pushes the skin with a pressure which is less than a predetermined level.

4. An apparatus for detecting vital functions, comprising:

sensing means adapted for attachment to a body and produces pulse wave signals corresponding to pulse waves of the body; and

cough determining means which determines an occurrence of a cough when an amplitude of the pulse waves on a p-systole side corresponding to a systolic phase of a heart of the body has exceeded a predetermined level and when the amplitude of the pulse wave signals on a p-diastole side corresponding to a succeeding diastolic phase of the heart of the body has exceeded a predetermined level.

5. The apparatus according to claim **4**, wherein the sensing means includes:

an optical device for projecting light onto a skin of the body to measure the pulse waves of the body; and

a buffer member arranged between the optical device and the skin so that the optical device of the skin side does

not come in contact with the skin or pushes the skin with a pressure which is less than a predetermined level.

6. The apparatus according to claim **4**, further comprising:

motion artifact determining means which determines an occurrence of a motion artifact based on the pulse waves detected by the sensing means, wherein

the cough determining means determines the occurrence of the cough when the motion artifact determining means additionally determines no occurrence of the motion artifact.

7. An apparatus for detecting vital functions, comprising:

sensing means adapted for attachment to a body and produces pulse wave signals corresponding to pulse waves of the body; and

cough determining means which determines an occurrence of a cough when an amplitude of the pulse waves on a p-systole side corresponding to a systolic phase of a heart of the body has increased by more than a predetermined level without causing a waveform of the pulse waves to be varied from a waveform of ordinary pulse waves which are produced in a calm state of the body.

8. The apparatus according to claim **7**, wherein the sensing means includes:

an optical device for projecting light onto a skin of the body to measure the pulse waves of the body; and

a buffer member arranged between the optical device and the skin so that the optical device of the skin side does not come in contact with the skin or pushes the skin with a pressure which is less than a predetermined level.

9. The apparatus according to claim **7**, further comprising:

motion artifact determining means which determines an occurrence of a motion artifact based on the pulse waves detected by the sensing means, wherein

the cough determining means determines the occurrence of the cough when the motion artifact determining means additionally determines no occurrence of the motion artifact.

10. An apparatus for detecting vital functions, comprising:

sensing means adapted for attachment to a body and produces pulse wave signals corresponding to pulse waves of the body; and

cough determining means which determines an occurrence of a cough when a change in a ratio AW**2**/BW**2** of an amplitude AW**2** of a base level of the pulse waves divided by an amplitude BW**2** of the pulse waves is within a predetermined value and within a predetermined period of time corresponding to a coughing.

11. The apparatus according to claim **10**, wherein the sensing means includes:

an optical device for projecting light onto a skin of the body to measure the pulse waves of the body; and

a buffer member arranged between the optical device and the skin so that the optical device of the skin side does not come in contact with the skin or pushes the skin with a pressure which is less than a predetermined level.

12. The apparatus according to claim **10**, further comprising:

motion artifact determining means which determines an occurrence of a motion artifact based on the pulse waves detected by the sensing means, wherein

the cough determining means determines the occurrence of the cough when the motion artifact determining means additionally determines no occurrence of the motion artifact.

13. An apparatus for detecting vital functions, comprising:

sensing means adapted for attachment to a body and produces pulse wave signals corresponding to pulse waves of the body; and

yawn determining means which determines an occurrence of a yawn when a base level of the pulse waves is lowered over a predetermined period corresponding to yawning.

14. The apparatus according to claim **13**, wherein

the yawn determining means determines the occurrence of a yawn when an amplitude of the pulse waves has become smaller than a predetermined level within a period in which the base level of the pulse waves is lower than a predetermined level.

15. An apparatus for detecting vital functions according to claim **14**, further comprising:

motion artifact checking means which determines an occurrence of a motion artifact, wherein

the yawn determining means determines the occurrence of the yawn when the motion artifact checking means additionally determines no occurrence of the motion artifact.

16. An apparatus for detecting vital functions according to claim **13**, further comprising:

motion artifact checking means which determines an occurrence of a motion artifact, wherein

the yawn determining means determines the occurrence of the yawn when the motion artifact checking means additionally determines no occurrence of the motion artifact.

17. The apparatus according to claim **16**, wherein

the motion artifact determining means determines an occurrence of a motion artifact when an amplitude on a p-diastole side corresponding to a diastolic phase of a heart of the body has exceeded a predetermined limit level that corresponds to a diastolic blood pressure of the body.

18. An apparatus according to claim **16** further comprising:

an actuator; and

control means which controls the actuator when the occurrence of the yawn is determined by the yawn determining means.

19. An apparatus for detecting vital functions, comprising:

sensing means adapted for attachment to a body and produces pulse wave signals corresponding to pulse waves of the body; and

yawn determining means which determines an occurrence of a yawn when an amplitude of the pulse waves on a p-systole side corresponding to a systolic phase of a heart of the body exceeds a predetermined level but when an amplitude of a succeeding pulse wave signals on a p-diastole side corresponding to a diastolic phase of the heart of the body does not become smaller than a predetermined level.

20. An apparatus for detecting vital functions according to claim **19** further comprising:

motion artifact checking means which determines an occurrence of a motion artifact, wherein

the yawn determining means determines the occurrence of the yawn when the motion artifact checking means additionally determines no occurrence of the motion artifact.

21. An apparatus for detecting vital functions, comprising:

sensing means adapted for attachment to a body and produces pulse wave signals corresponding to pulse waves of the body; and

yawn determining means which determines an occurrence of a yawn when a whole amplitude of pulse waves of a sum of amplitudes on a p-systole side and of amplitudes on a p-diastole side becomes smaller than a predetermined level after the amplitudes on p-systole side cor-

responding to the systolic phase of a heart of the body has exceeded a predetermined level without causing the waveform of the pulse waves to be varied from the waveform of ordinary pulse waves.

22. An apparatus for detecting vital functions according to claim **21**, further comprising:

motion artifact checking means which determines an occurrence of a motion artifact, wherein

the yawn determining means determines the occurrence of the yawn when the motion artifact checking means additionally determines no occurrence of the motion artifact.

23. An apparatus for detecting vital functions, comprising:

sensing means adapted for attachment to a body and produces pulse wave signals corresponding to pulse waves of the body;

respiration waveform calculation means which finds a respiration waveform that represents a respiration condition from the pulse waves; and

yawn determining means which determines an occurrence of a yawn when the amplitude of the respiration waveform is not smaller than a predetermined level and when a double triangular wave of an obtuse angle is detected in which two peaks of the respiration waveform consecutively exceed a predetermined level.

24. An apparatus for detecting vital functions according to claim **23**, further comprising:

motion artifact checking means which determines an occurrence of a motion artifact, wherein

the yawn determining means determines the occurrence of the yawn when the motion artifact checking means additionally determines no occurrence of the motion artifact.

25. An apparatus for detecting vital functions, comprising:

sensing means adapted for attachment to a body and produces pulse wave signals corresponding to pulse waves of the body;

yawn determining means which determines an occurrence of a yawn when a change in a ratio AW**2**/BW**2** of an amplitude AW**2** of a base level of the pulse waves divided by an amplitude BW**2** of the pulse waves is not smaller than a predetermined level and within a predetermined period of time corresponding to a yawning.

26. An apparatus for detecting vital functions according to claim **25**, further comprising:

motion artifact checking means which determines an occurrence of a motion artifact, wherein

the yawn determining means determines the occurrence of the yawn when the motion artifact checking means additionally determines no occurrence of the motion artifact.

* * * * *

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent of:	Poeze et al.	
U.S. Patent No.:	10,258,266	Attorney Docket No.: 50095-0007IP1
Issue Date:	April 16, 2019	
Appl. Serial No.:	16/212,537	
Filing Date:	Dec. 6, 2018	
Title:	MULTI-STREAM DATA COLLECTION SYSTEM FOR NONINVASIVE MEASUREMENT OF BLOOD CONSTITUENTS	

SECOND DECLARATION OF DR. THOMAS W. KENNY

I hereby declare that all statements made of my own knowledge are true and that all statements made on information and belief are believed to be true. I further declare that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of the Title 18 of the United States Code.

Dated: December 2, 2021 By: ________________________

Thomas W. Kenny, Ph.D.

4. I have no financial interest in the party or in the outcome of this proceeding. I am being compensated for my work as an expert on an hourly basis. My compensation is not dependent on the outcome of these proceedings or the content of my opinions.

5. In writing this declaration, I have considered the following: my own knowledge and experience, including my work experience in the fields of mechanical engineering, computer science, biomedical engineering, and electrical engineer; my experience in teaching those subjects; and my experience in working with others involved in those fields. In addition, I have analyzed various publications and materials, in addition to other materials I cite in my declaration.

6. My opinions, as explained below, are based on my education, experience, and expertise in the fields relating to the ’266 Patent. Unless otherwise stated, my testimony below refers to the knowledge of one of ordinary skill in the fields as of the Critical Date, or before.

II. Ground 1 Establishes Obviousness

A. Inokawa’s lens enhances the light-gathering ability of Aizawa

7. As I previously explained in the Original Declaration, Inokawa ***very generally*** describes a “lens [that] makes it possible to increase the light-gathering ability” of a reflectance type pulse sensor, APPLE-1008, [0015], [0058], FIG. 2, and, based on this disclosure, a POSITA would have been motivated to incorporate “an Inokawa-like lens into the cover of Aizawa to increase the light collection efficiency....” APPLE-1003, ¶¶86-89. In a significant extrapolation from the very simple and

purely illustrative description in Inokawa, Patent Owner provides two incorrect arguments. First, Patent Owner claims that Inokawa's disclosure is narrowly-limited to a particular lens that somehow is only capable of operation with peripheral emitters and a central detector. Second, the Patent Owner claims that the lens of Inokawa directs all incoming light rays "to the center of the sensor" and would "direct light ***away*** from the ***periphery***-located detectors as in Aizawa," regardless of the direction of light propagation of each ray, which is a violation of elementary laws of light propagation that would be familiar to a POSITA. POR, 16, 20; *see also* APPLE-1034, 40:4-11 ("...as I describe in my Declaration...if you have a convex surface...***all light reflected*** or otherwise would be condensed or directed towards the center."). Based on these two incorrect claims, the Patent Owner insists that there would be no motivation to combine.

8. Patent Owner's misinformed understanding of Inokawa's lens as well as lenses in general is demonstrated by their description of Inokawa's lens 27 as "focus[ing] light from LEDs (21, 23)...***to a single detector (25) in the center***" and "direct[ing] incoming light ***to the centrally located detector***." POR, 14; *see also* APPLE-1034, 40:4-11 ("...as I describe in my Declaration...if you have a convex surface...***all light*** reflected or otherwise would be condensed or directed towards the center.").

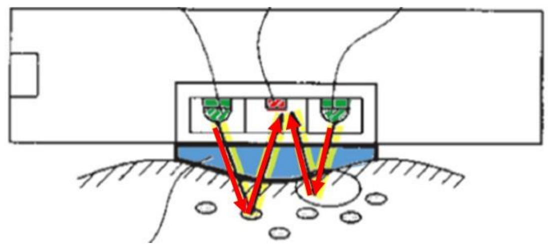
9. A correct understanding of Inokawa's lens as well as of reflectance type pulse sensors in general (like those disclosed by each of Aizawa, Inokawa, and Mendelson-1988) readily exposes Patent Owner's flawed rationale. Indeed, as I noted during

deposition, a POSITA would understand that Inokawa's lens generally improves "light concentration at pretty much all of the locations under the curvature of the lens," as opposed to only at a single point at the center as asserted by Patent Owner. Ex. 2006, 164:8-16. Indeed, as further explained below, a POSITA would have understood the following to be true—that a cover featuring a convex protrusion would improve Aizawa's signal-to-noise ratio by causing more light backscattered from tissue to strike Aizawa's photodetectors than would have with a flat cover. APPLE-1051, 52, 86, 90; APPLE-1052, 84, 87-92, 135-141; APPLE-1046, 803-805; APPLE-1006, FIGS. 1(a)-1(b). The convex cover enhances the light-gathering ability of Aizawa's sensor.

i. Masimo ignores the well-known principle of reversibility

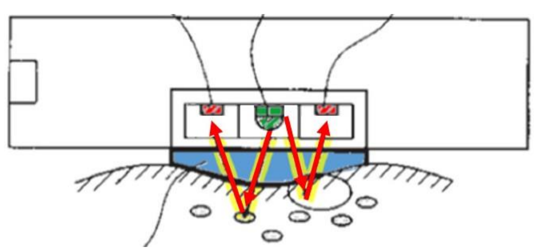
10. The well-known optical ***principle of reversibility*** readily dispels Masimo's claim that "a convex cover condenses light towards the center of the sensor and away from the periphery," when applied to Aizawa. POR, 16; APPLE-1052, 87-92; APPLE-1049, 106-111. Specifically, according to the principle of reversibility, "a ray going from P to S will trace the same route as one from S to P." APPLE-1052, 92, 84; APPLE-1049, 101, 110; APPLE-1036, 80:20-82:20. Importantly, the principle dictates that rays that are not completely absorbed by user tissue will propagate in a reversible manner. In other words, every ray that completes a path through tissue from an LED to a detector would trace an identical path through that tissue in reverse, if the positions of the LED emitting the ray and the receiving detector were swapped.

APPLE-1052, 92. To help explain, I have annotated Inokawa's FIG. 2 (presented below) to illustrate the principle of reversibility applied in the context of a reflective optical physiological monitor. As shown, Inokawa's FIG. 2, illustrates two example ray paths from surrounding LEDs (green) to a central detector (red):



APPLE-1008, FIG. 2 (annotated)

11. As a consequence of the principle of reversibility, a POSITA would have understood that if the LED/detector configuration were swapped, as in Aizawa, the two example rays would travel identical paths in reverse, from a central LED (red) to surrounding detectors (green). A POSITA would have understood that, for these rays, any condensing/directing/focusing benefit achieved by Inokawa's cover (blue) under the original configuration would be identically achieved under the reversed configuration:



APPLE-1008, FIG. 2 (annotated)

12. When factoring in additional scattering that may occur when light is reflected within human tissue, reversibility holds for each of the rays that are not completely absorbed; consequently, "if we're concerned with the impact of the lens on the system,

it's absolutely reversible." EX. 2006, 209:19-21, 207:9-209:21 ("one could look at any particular randomly scattered path…and the reversibility principle applies to all of the pieces [of that path] and, therefore, applies to the aggregate").

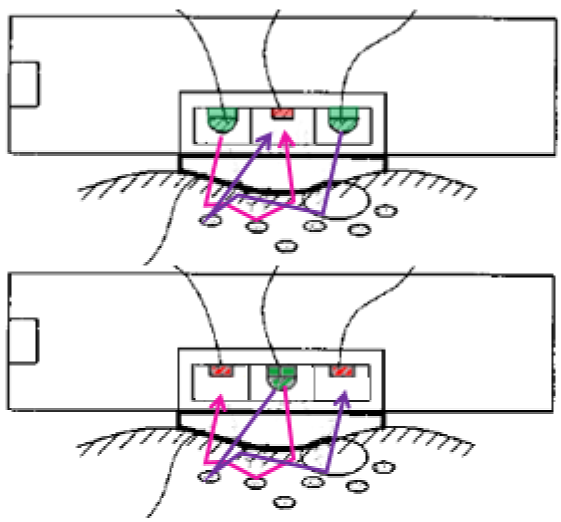
13. An example of reversibility in a situation with diffuse light, such as is present when LEDs illuminate tissue, is shown below from Hecht's Figure 4.12.

Figure 4.12 (a) Specular reflection. (b) Diffuse reflection. (Photos courtesy Donald Dunitz.)

14. In this figure 4.12a, collimated light is incident on a smooth surface, and exhibits specular reflection, in which parallel light rays encounter and are reflected from the surface and remain parallel. A POSITA would certainly understand specular reflection. In the case of the reflection as shown in Figure 4.12b, the random roughness of the surface scatters the incoming rays into many directions, and the resulting light would appear to be diffuse. However, even in this circumstance, the principle of reversibility applies–each individual ray can be reversed such that a ray travelling to the surface and scattered in a random direction can be followed backwards along exactly the same path.

15. In more detail, and as shown with respect to the example paths illustrated below (which include scattering within tissue), each of the countless photons

travelling through the system must abide by Fermat's principle. APPLE-1049, 106-111. Consequently, even when accounting for various random redirections and partial absorptions, each photon traveling between a detector and an LED would take the quickest (and identical) path along the segments between each scattering event, even if the positions of the detector and LED were swapped.



16. To better understand the effect of a convex lens on the propagation of light rays towards or away from the different LEDs or detectors, the first and last segment of the light path may be representative of the light propagation of the various light rays. In the figures above, starting at the upper left, there is a pink-colored light ray emerging from the green LED and passing through the convex lens and entering the tissue. On the lower left, there is a pink-colored light ray leaving the tissue and entering the convex lens. As drawn, these rays are the same in position and orientation, except that the direction is exactly reversed. This illustration is consistent with the Principle of Reversibility as applied to this pair of possible light rays. According to the principle of reversibility, the upper light path from the LED to the

first interaction with a corpuscle is exactly reversed. This same behavioral pattern applies to all of the segments of the many light paths that cross the interface at the surface of the convex lens. Importantly, in this example, the convex lens does not refract the incoming ray in a different direction from the outgoing ray, e.g., in a direction towards the center different from the outgoing ray. As required by the principle of reversibility, this incoming ray follows the same path as the outgoing ray, except in the reverse direction. This statement is true for every segment of these light paths that crosses the interface between the tissue and the convex lens. Any ray of light that successfully traverses a path from the LED to the detector, that path already accounts for the random scattering as that scattering is what allowed the ray to go from the LED to a detector along the path to thereby be subsequently detected by the detector. A POSITA would have understood that the path is an aggregation of multiple segments and that the path is reversible as each of its segments would be reversible, consistent with Fermat's principle.

17. The statement about the reversibility of the segments of the light path which cross the interface between tissue and convex lens is consistent with the well-known and well-established Snell's law, which provides a simple algebraic relation between the angles of incidence and refraction as determined by the two indices of refraction. And Snell's law supports the basic understanding that the path of the light rays to/from a scattering event across the interface to/from the convex lens and on to/from the LED or photodetector must be reversible.

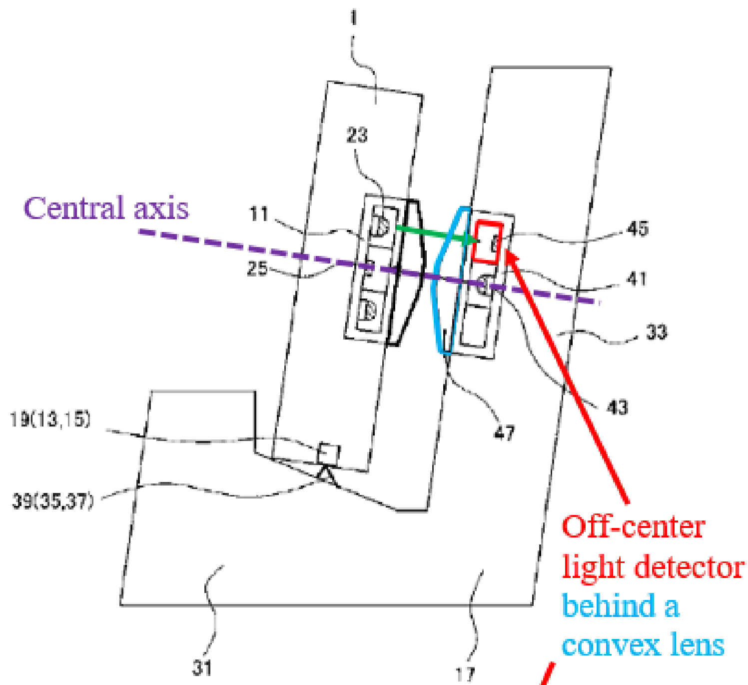
18. Based on this understanding of light rays and Snell's law, a POSITA would have understood that the positions of the emitters and detectors can be swapped in the proposed combination, and that the light paths from the initial situation would be reversed in the altered situation.

19. When confronted with this basic principle of reversibility during deposition, Dr. Madisetti refused to acknowledge it, even going so far as to express ignorance of "Fermat's principle, ***whatever that is***." APPLE-1034, 89:12-19. Yet Fermat's principle, which states that a path taken by a light ray between two points is one that can be traveled in the least time, regardless of the direction of travel, is one of the most fundamental concepts in optics/physics and plainly requires the basic principle of reversibility. APPLE-1052, 87-92; APPLE-1049, 106-111. This is in no way a new theory, as this core concept dates back many years, and is offered in Aizawa itself. Indeed, ***Aizawa recognizes this reversibility***, stating that while the configurations depicted include a central emitter surrounded by detectors, the "same effect can be obtained when…a plurality of light emitting diodes 21 are disposed around the photodetector 22." APPLE-1006, [0033]; EX. 2006, 209:19-21.

20. Masimo's technically and factually flawed argument is exposed by multiple prior art references, including the Ohsaki and Inokawa references which are the key elements of our combinations. As shown in the figures below, Ohsaki and Inokawa both show embodiments which use a convex lens to direct light to detectors that are not located at the center of a sensor. APPLE-1014, FIG. 2; APPLE-1008, FIG. 3.

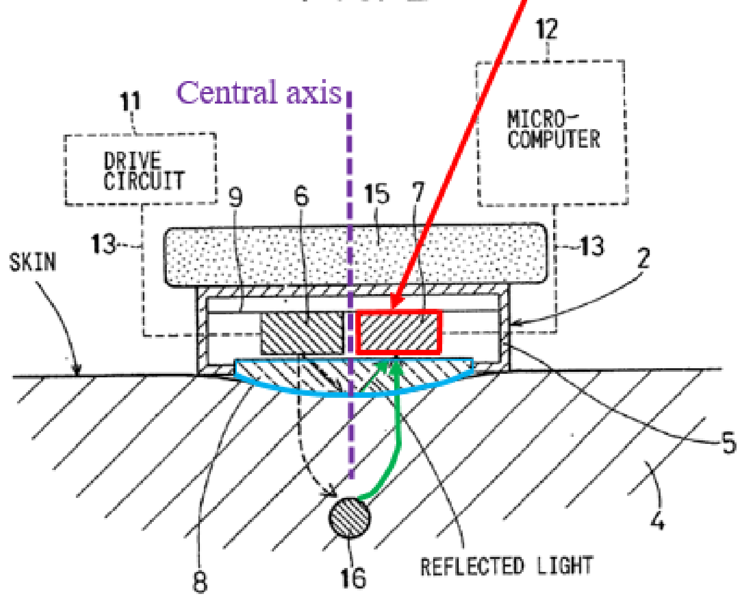
In Inokawa's Figure 2, an off-center emitter and sensor are configured to send and receive text messages, and are capable of success, even though the detector is not positioned at the center.

(FIG. 3)



APPLE-1008, FIG. 3

FIG. 2



APPLE-1014, FIG. 2

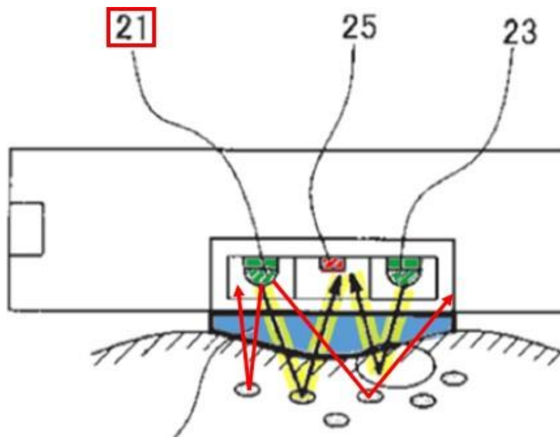
21. If, as asserted by the Patent Owner, a convex lens is required to condense, direct, or focus the light to the center, the embodiments disclosed by Ohsaki and Inokawa would all fail because there is no detector at the center to detect all of the light that would be directed towards the center by the convex board. The Ohsaki and Inokawa embodiments (reproduced above) do not show or otherwise teach that its convex board directs all light towards the center.

22. In short, based at least on the principle of reversibility, a POSITA would have understood that both configurations of LEDs and detectors—*i.e.*, with the LED at the center as in Aizawa or with the detector at the center as in Inokawa—would identically benefit from the enhanced light-gathering ability of a convex lens/protrusion.

ii. Masimo ignores the behavior of scattered light in a reflectance-type pulse sensor

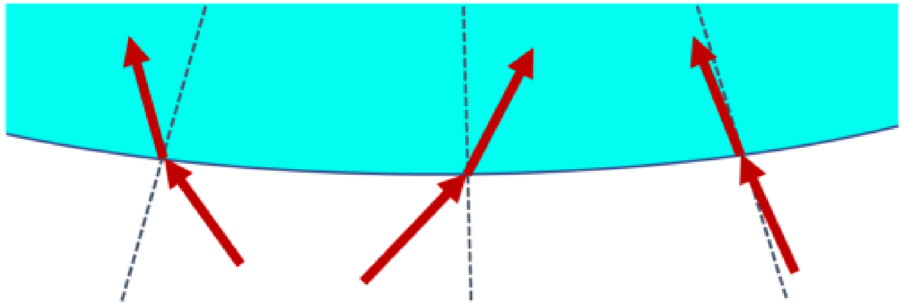
23. Because Aizawa is a reflectance-type pulse sensor that receives diffuse, backscattered light from the measurement site, its cover/lens cannot focus all incoming light toward the sensor's center. Ex. 2006, 163:12-164:2 ("A lens in general…doesn't produce a single focal point"). Indeed, reflectance-type sensors work by detecting light that has been "partially reflected, transmitted, absorbed, and scattered by the skin and other tissues and the blood before it reaches the detector." APPLE-1051, 86. A POSITA would have understood that light which backscatters from the measurement site after diffusing through tissue reaches the active detection area from various random directions and angles. APPLE-1046, 803; APPLE-1051, 90, 52.

24. As noted above, basic law of refraction, namely Snell's law, dictates this behavior of light. APPLE-1052, 84; APPLE-1049, 101; APPLE-1036, 80:20-82:20; APPLE-1051, 52, 86, 90. For example, referring to Masimo's version of Inokawa's FIG. 2, further annotated below to show additional rays of light emitted from LED 21, it is clearly seen how some of the reflected/scattered light from the measurement site does not reach Inokawa's centrally located detector:



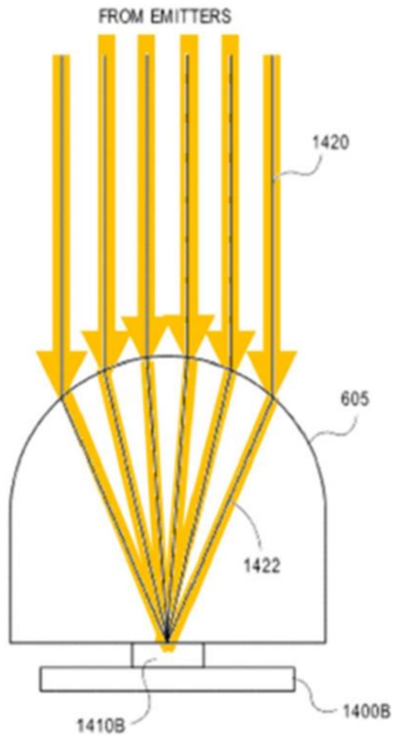
APPLE-1008, FIG. 2 (annotated); POR, 14.

25. For these and countless other rays that are not shown, there is simply no way for a cover to focus all light at the center of the sensor device. APPLE-1052, 84; APPLE-1049, 101; APPLE-1036, 80:20-82:20. The illustration I provide below shows how Snell's law determines a direction of a backscattered ray within a convex cover, thus providing a stark contrast to Masimo's assertions that all such rays must be redirected to or towards the center:



26. Indeed, far from focusing light to the center as Masimo contends, Ohsaki's convex cover provides a slight refracting effect, such that light rays that may have otherwise missed the detection area are instead directed toward that area as they pass through the interface provided by the cover. This is particularly true in configurations like Aizawa's in which light detectors are arranged symmetrically about a central light source, so as to enable backscattered light to be detected within a circular active detection area surrounding that source. APPLE-1051, 86, 90. The slight refracting effect is a consequence of the similar indices of refraction between human tissue and a typical cover material (e.g., acrylic). APPLE-1044, 1486; APPLE-1045, 1484).

27. To support the misguided notion that a convex cover focuses all incoming light at the center, Masimo relies heavily on the '266 Patent's FIG. 14B (reproduced below):



APPLE-1001, FIG. 14B (as annotated at POR, 18-19, 26)

28. Masimo and Dr. Madisetti treat this figure as an illustration of the behavior of all convex surfaces with respect to all types of light, and conclude that "a convex surface condenses light away from the periphery and towards the sensor's center." POR, 16; APPLE-1034 ("…a POSA viewing [FIG. 14B]…would understand that light, ***all light***, light from the measurement site is being focused towards the center").

29. But the incoming collimated light shown in FIG. 14B is not an accurate representation of light that has been reflected from a tissue measurement site. The light rays (1420) shown in FIG. 14B are collimated (i.e., travelling paths parallel to one another), and each light ray's path is perpendicular to the detecting surface.

30. While each of Inokawa, Aizawa, and Mendelson-1988 are directed to a reflectance-type pulse sensor that detects light that has been backscattered from the

measurement site, the scenario depicted in FIG. 14B shows a transmittance-type configuration where collimated or nearly-collimated light is "attenuated by body tissue," not backscattered by it. APPLE-1001, 35:65-67. Indeed, FIG. 14I of the '266 Patent puts FIG. 14B in proper context, showing how light from the emitters is transmitted through the entire finger/tissue before being received by the detectors on the other side:

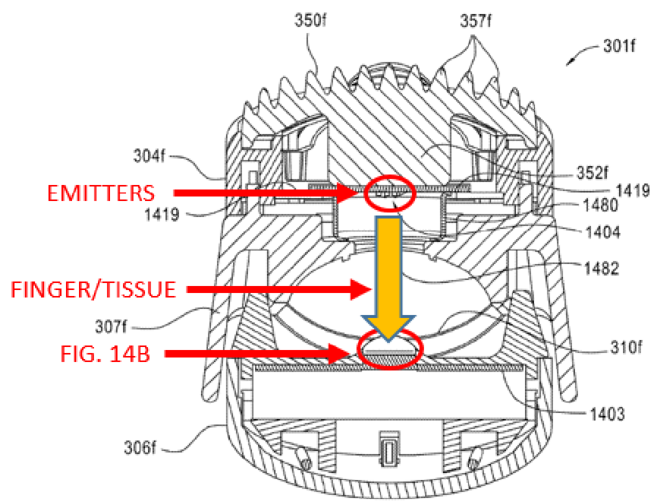
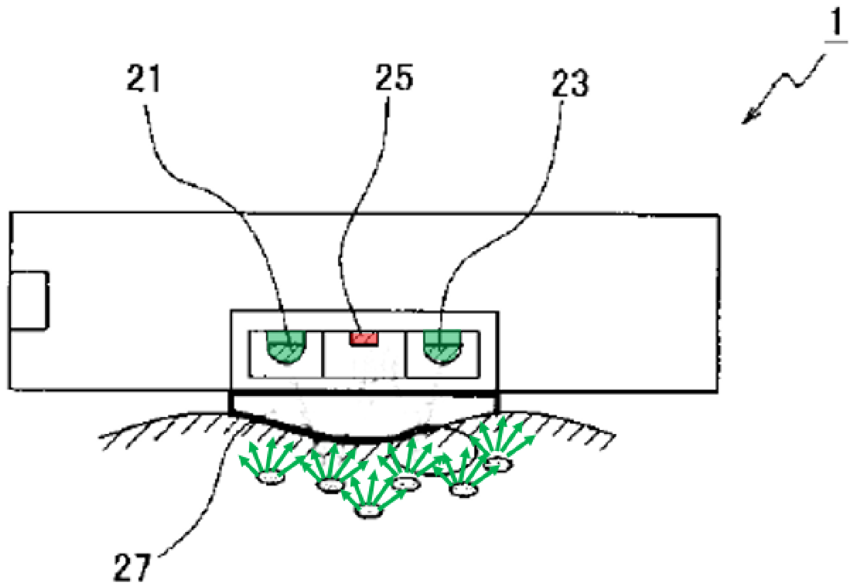


FIG. 14I

31. By contrast, the detector(s) of reflectance type pulse detectors detect light that has been "partially reflected, transmitted, absorbed, and scattered by the skin and other tissues and the blood before it reaches the detector." APPLE-1051, 86. For example, a POSITA would have understood from Aizawa's FIG. 1(a) that light that backscatters from the measurement site after diffusing through tissue reaches the circular active detection area provided by Aizawa's detectors from various random directions and angles, as opposed to all light entering from the same direction and at

the same angle as shown above in FIG. 14B. APPLE-1051, 52, 86, 90; APPLE-1046, 803-805; *see also* APPLE-1012, FIG. 7. Even for the collimated light shown in FIG. 14B, the focusing of light at the center only occurs if the light beam also happens to be perfectly aligned with the axis of symmetry of the lens. If for example, collimated light were to enter the FIG. 14B lens at any other angle, the light would focus at a different location in the focal plane. Further, if the light were not collimated, so that rays enter the lens with a very wide range of incident angles, there would be no focus at all, and many rays will be deflected away from the center. Moreover, since "the center" takes up a very small portion of the total area under the lens, the majority of rays associated with diffuse light entering the lens would arrive at locations away from the center.

32. The light rays from a diffuse light source, such as the LED-illuminated tissue near a pulse wave sensor or a pulse oximeter, include a very wide range of angles and directions, and cannot be focused to a single point/area with optical elements such as lenses and more general convex surfaces. The example figure below illustrates light rays backscattered by tissue toward a convex lens; as consequence of this backscattering, a POSITA would have understood that the backscattered light will encounter the interface provided by the convex board/lens at all locations from a wide range of angles. This pattern of incoming light cannot be focused by a convex lens towards any single location.



APPLE-1052, 141 (annotated)

33. To the extent Masimo contends that only *some* light is directed “towards the center” and away from Aizawa’s detectors in a way that discourages combination, such arguments also fail. Indeed, far from *focusing* light to a single central point, a POSITA would have understood that Ohsaki’s cover provides a slight refracting effect, such that light rays that may have missed the active detection area are instead directed toward that area as they pass through the interface provided by the lens. APPLE-1051, 52; APPLE-1007, [0015]; APPLE-1052, 87-92, 135-141; APPLE-1034, 60:7-61:6, 70:8-18.

34. Patent Owner and Dr. Madisetti’s reliance on drawings provided in paragraphs 119-120 of my Original Declaration filed in IPR2020-01520 for justification of their understanding of Inokawa’s lens is similarly misplaced. POR, 16-18; APPLE-1041, 41:7-22, 60:7-61:6. Far from demonstrating the false notion that a convex lens directs all light to the center, these drawings I previously provided are merely

simplified diagrams included to illustrate, as per dependent claim 12, one example scenario (based on just one ray and one corpuscle) where a light permeable cover can "reduce a mean path length of light traveling to the at least four detectors." Ex. 2020, ¶¶119-120. As previously illustrated, there are many other rays that would intersect the interface between the tissue and the lens at different locations and with different angles of incidence, and the effect of the lens on this variety of rays is not nearly as simple as the statements provided by Dr. Madisetti. There is simply no possibility of any lens focusing all incoming rays from a diffuse light source toward a central location.

B. A POSITA would have been motivated to add a second LED to Aizawa

35. As laid out in detail in my Original Declaration, a POSITA would have been motivated to add a second emitter operating at a different wavelength to Aizawa in order to allow for a more reliable pulse measurement that takes into account and corrects for inaccurate readings stemming from body movement. APPLE-1003, ¶¶69-81.

36. Patent Owner, however, suggests that such motivation is flawed because "Aizawa...expressly states that it provides a "device for ***computing*** the ***amount*** of motion load from the pulse rate.'" POR, 39. But Patent Owner fails to explain how Aizawa senses and computes motion load. Indeed, Aizawa is completely silent on this point. Moreover, while Patent Owner contends that Aizawa "account[s] for" motion, Aizawa does not even

say whether it uses the computed motion load to improve the detection signal. Patent Owner further fails to rebut that adding a second LED having a second wavelength, as per Inokawa, will "allow for a more reliable" reading that compensates for body motion. APPLE-1003, ¶72. Like I explained during my deposition, adding a second LED at a different wavelength to Aizawa's single LED design would allow it to obtain a more reliable pulse measurement by allowing the system to "measur[e] pulse rate and motion load during the same time" by operating a separate LED dedicated to sensing motion. Ex. 2007, 401:11-402:4. Moreover, having two separate signals that are respectively dedicated to measuring pulse and body motion, as per Inokawa, will allow Aizawa's system to "take into account and correct for inaccurate readings related to body movement" by subtracting the "signal component corresponding to body movement [] from the pulse signal to help better isolate the desired pulse data." APPLE-1003, ¶72.

37. By using two wavelengths, it is possible to record two independent signal waveforms at the same time from the same site. As explained above, each reflected signal includes some dependence on the physiological parameter, and on the movement of the sensor relative to the measurement site. Because it is possible to choose different wavelengths of light so as to have one signal with strongest dependence on the physiological parameter

and the second signal with the strongest dependence on the movement of the sensor, the signals can be processed in a way to compensate for movement and create a more reliable measurement of the physiological parameter. The use of two or more separate wavelengths to obtain independent measures of the physiological parameter and error sources such as body movement, was well-known at the time of the invention, and it would have been obvious for a POSITA to consider the use of a second wavelength LED to capture these benefits.

38. Inokawa provides a second and independent motivation for adding a second LED having a different wavelength, namely the ability to "improve data transmission accuracy by using the second LED...to transmit checksum information such that 'the accuracy of data can be increased." APPLE-1008, [0111], [0044], [0048]; APPLE-1003, ¶78. The fact that "Inokawa states that it can accomplish transmission with a ***single*** LED" does not take away from the fact that a POSITA would nevertheless have been motivated to look to the two-LED implementation of Inokawa to further improve accuracy. POR, 41; Ex. 2007, 407:7-408:20. Despite Patent Owner's contention that I "acknowledged that POSITA wanting to maintain a wireless data transmission approach [in Aizawa] would not switch to the base station transmission approach of Inokawa," POR, 42, a full reading of transcript reveals that I was simply making it very clear that if "they've

already decided not to use a base station transmission device, then they probably wouldn't switch to one." Ex. 2007, 416:5-15. As for Patent Owner's assertion that Aizawa's goal is "real-time measuring," I note that there is no disclosure in Aizawa indicating that such measured data must also be transmitted externally in real-time. POR, 40. Moreover, a POSITA would have been capable of balancing potential benefits associated with different data transmission approaches, for instance improved transmission accuracy on one hand and quicker transmission on the other.

39. Patent Owner additionally argues that "Petitioner fails to address other complications that would result from adding an extra LED to a physiological sensor," such as the potential for "thermal interference." POR, 42. But as I again explained during my deposition and reiterate here, such minor issues are "part of what I understand someone of ordinary skill in the art would bring...to the problem and would know how to make the changes needed." Ex. 2007, 384:8-388:12.

C. A POSITA would have been motivated to modify Aizawa in view of Ohsaki to include a convex protrusion

40. As explained in my Original Declaration, "Ohsaki teaches that adding a convex surface...can help prevent the device from slipping on the tissue of the wearer compared to using a flat cover without such protrusion" and that "a POSITA seeking to achieve improved adhesion between the detector and the skin, as expressly recognized in Aizawa, would have been motivated and readily able to modify

Aizawa's acrylic plate to have a convex shape as in Ohsaki." APPLE-1003, ¶¶127-128 (citing to APPLE-1014, [0025]; APPLE-1006, [0026], [0030]).

41. Patent Owner, rather than attempting to directly rebut this rationale, focuses on arguments that are factually flawed and legally irrelevant. Specifically, Patent Owner contends that Ohsaki's "convex surface must have ***longitudinal directionality***," and that "Ohsaki indicates that its convex surface ***only prevents slipping on the backhand side*** (i.e., watch-side) of the user's wrist." POR, 45. Patent Owner further asserts that the shape of Ohsaki's board must be limited to a long, narrow rectangular shape while ignoring that the specification includes no specific limitation on the shape of the board.

42. Notably absent from the POR is how Ohsaki ***actually*** describes the benefits associated with its convex surface. For example, Ohsaki contrasts a "convex detecting surface" from a "flat detecting surface," and explains that "if the translucent board 8 has a flat surface, the detected pulse wave is adversely affected by the movement of the user's wrist," but that if "the translucent board 8 has a convex surface…variation of the amount of the reflected light…that reaches the light receiving element 7 is suppressed." APPLE-1014, ¶[0025]. But a POSITA would have understood from such teachings of Ohsaki that the advantages of a light permeable protruding convex cover could apply regardless of any alleged longitudinal directionality of Ohsaki's cover and regardless of where on the body such a convex cover was placed. *See* APPLE-1014, ¶¶[0015], [0017], [0025], FIGS.

1, 2, 4A, 4B. This is because Ohsaki was relied upon not for its exact cover configuration but rather for the rather obvious concept that a convex surface protruding into a user's skin will prevent slippage, regardless of any directionality that may or may not exist with respect to such convex surface and regardless of where on the human body it is located. *See* Ex. 2012, 91, 87; APPLE-1014, ¶¶[0015], [0017], [0025], FIGS. 1, 2, 4A, 4B. In fact, Ohsaki says nothing about the exact dimensions or even anything specific about the required shape of the board, except that it provides a convex protrusion. A POSITA would seek to combine the board of Ohsaki with Aizawa by making reasonable modifications as needed to ensure that the board of Ohsaki was compatible with the other features present in Aizawa. A POSITA would find it obvious to consider selecting a shape for the board that is consistent with the shape of the system presented in Aizawa, and would expect that the benefits associated with the convex board of Ohsaki would be present in the combination. And adding a convex surface to Aizawa's flat plate will serve to ***improve*** its tendency to not slip off, not take away from it, since it is well understood that physically extending into the tissue and displacing the tissue with a protrusion provides an additional adhesive effect. Aizawa provides a plate that improves adhesion with the surface. Ohsaki further teaches that the convex protrusion provides "intimate contact" with the tissue, which helps prevent the detecting element from slipping off. These benefits are clearly related and complimentary, and a POSITA would appreciate that modifying the plate of Aizawa to include a convex

protrusion as in Ohsaki would provide improved performance, and that these benefits can be obtained by making obvious modifications to the board in Ohsaki to accommodate the shape of Aizawa.

43. Indeed, Ohsaki's specification and claim language reinforce that Ohsaki's description would not have been understood as limited to one side of the wrist. For example, Ohsaki explains that "the detecting element 2…may be worn on the back side of the user's forearm" as one form of modification. *See* APPLE-1014, [0030], [0028] (providing a section titled "[m]odifications"). The gap between the ulna and radius bones at the forearm is even greater than the gap between bones at the wrist, which is already wide enough to easily accommodate a range of sensor sizes and shapes, including circular shapes. In addition, Ohsaki's claim 1 states that "the detecting element is constructed to be worn on a back side of a user's wrist ***or a user's forearm***." *See also* APPLE-1014, claims 1-2. As another example, Ohsaki's independent claim 5 and dependent claim 6 state that "the detecting element is constructed to be worn on a user's wrist or a user's forearm," ***without even mentioning a backside*** of the wrist or forearm. *See also* APPLE-1014, Claims 6-8. A POSITA would have understood that Ohsaki's benefits provide improvements when the sensor is placed on either side of the user's wrist or forearm. APPLE-1014, [0025], FIGS. 4A, 4B. And while Masimo appears to contend that Ohsaki teaches that a convex cover at the front (palm) side of the wrist somehow *increases* the tendency to slip, this is an argument that is nowhere supported by Ohsaki. For

instance, paragraph 23 and FIGS. 3A-3B of Ohsaki that Masimo points to as allegedly providing support for this incorrect argument mentions nothing about the flat/convex nature of the cover and is instead merely demonstrating that pulse detection is generally less reliable when the user is in motion (and thus would benefit from changes such as adding a convex cover). APPLE-1014, [0024], FIGS. 4A, 4B

44. POR presents several arguments with respect to Ground 1 that are premised on Ohsaki ***requiring*** the detecting element to be worn on a back side of a user's wrist or a user's forearm. Because Ohsaki requires no such location for the translucent board 8, these arguments fail.

III. Ground 2 Establishes Obviousness

45. As I further clarify below in response to Patent Owner's arguments, claims 1-6, 8-16, 18, and 19 are rendered obvious by the combination of Mendelson-1988 and Inokawa (Ground 2).

A. Inokawa's lens similarly enhances the light-gathering ability of Mendelson-1988

46. Similar to their rebuttal of the Aizawa-based grounds, Patent Owner contends that (1) "Inokawa's convex lens focused light on a ***centrally located*** detector" and (2) as a result, incorporating such a lens to Mendelson-1988 would cause the "lens to direct light ***away*** from the detectors" based on Mendelson-1988's use of centrally-located LEDs. POR, 49-51. For reasons discussed at length above, basic optical principles and a proper understanding of reflectance-type sensors as in Aizawa, Inokawa, and Mendelson-1988 would have led a POSITA to understand that adding

an Inokawa-like lens to Mendelson-1988 would result in additional benefits such as enhanced light-gathering ability and improved signal-to-noise ratio. Again, as noted above, Patent Owner's fundamentally flawed characterization of the lens of Inokawa as "focusing [light] on a single central detector" runs contrary to basic principles of optics and how lenses work.

B. Mendelson-1988 in view of Inokawa includes the claimed cover

47. As I previously explained, the Mendelson-1988-Inokawa combination provides protruded epoxy cover that acts as a lens and also covers the detectors. APPLE-1003, ¶¶134-143. Patent Owner argues, however, that "the '266 Patent distinguishes a resin on a surface from a cover" and, as a result, the modified Mendelson-1988 device lacks a cover. POR, 52-53. Patent Owner further argues that the convex cover in the contemplated combination is somehow not a cover because "it is part of an undifferentiated mass of material." *Id.*

48. A POSITA would understand the plain meaning of cover to be merely "something that protects, shelters, or guards." APPLE-1050. Both instances of the "light permeable cover" as I previously identified are clearly covers that serve to protect. There is nothing in the specification of the '266 patent itself that suggests that some special meaning is attributed to the term "cover" as used in the patent.

49. Patent Owner mischaracterizes my deposition testimony to make it sound like I agreed that "sealing resin" is somehow different from a cover. POR, 52-53 (citing

to Ex. 2009, 395:22-396:17). My actual testimony, if one reads it fully, clearly shows that no such statement was made. *See* Ex. 2009, 396:9-17 ("Q. So [using a sealing resin] would be one way to protect the components without using a cover, correct? A. There are many ways to protect the elements other than using a cover. The purpose of the cover in this combination is also to improve adhesion and to improve light gathering for the operation of the system."). Rather, I was merely clarifying that using a sealing resin is "a pretty common way to protect electronic components." *Id.*, 395:22-396:8.

50. Moreover, while Patent Owner points to a cherry-picked passage from the '266 Patent to suggest that it distinguishes "cover" from "resin epoxies," POR, 52-53 (citing APPLE-1001, 36:37-46 ("[The cover] can protect...***more effectively*** than currently-available ***resin epoxies***."), Patent Owner failed to reproduce the rest of the sentence, which reads: "...more effectively than currently-available resin epoxies, ***which are sometimes applied to solder joints between conductors and detectors***." APPLE-1001, 36:37-46. That is, the epoxy resin to which the '266 Patent compares its cover is not the epoxy cover as contemplated in the Mendelson-1988 combination but rather epoxy that is applied to solder joints.

51. As for Patent Owner's argument that "an undifferentiated mass of resin" cannot form the claimed cover, I initially note that the plain meaning of "cover" does not require that the cover be a distinct structure that is completely separated and distinct from surrounding structures. *See* APPLE-1050. Nor does Patent Owner

expressly argue for such a construction of "cover."

52. Moreover, to the extent the claimed "cover" must be "distinct" from all other components, I previously explained how a POSITA, looking at conventional epoxy processing techniques such as those found in Nishikawa, would have added an additional epoxy lens layer separately on top of the epoxy encapsulation layer underneath, thereby providing a separate and differentiated mass of material to serve as the cover. APPLE-1003, ¶140-142 (citing to APPLE-1023, [0034]-[0038], FIGS. 5-6).

C. Mendelson-1988 in view of Inokawa renders obvious a "circular housing" with a "cover"

53. Regarding this feature, I previously explained that there was nothing new or inventive about changing a rectangular housing for a circular one and that a POSITA, among other things because microelectronic packaging as used in Mendelson-1988 comes in various shapes and sizes. APPLE-1003, ¶¶160-162. Patent Owner rebuts this simple change in design by arguing that "[a] POSITA would have no particular motivation to change the shape unless a POSITA perceived some benefit in doing so." POR, 54-55. But there is nothing in the '266 Patent or in the POR that explains how the particular housing shape solves some problem or presents some unexpected result. Rather, a POSITA would have simply recognized that housing shape is a non-inventive feature and that it would have been quite routine to use a differently shaped housing. *See* APPLE-1003, ¶¶160-162. Indeed, given that many other references, such as Mendelson-799 (APPLE-1025), explicitly show the use of circular

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APPLE INC.
Petitioner,

v.

MASIMO CORPORATION,
Patent Owner.

Case IPR2021-00208
U.S. Patent 10,258,266

DECLARATION OF VIJAY K. MADISETTI, PH.D.

Masimo Ex. 2004
Apple v. Masimo
IPR2021-00208

47. Dr. Kenny provides no analysis why a POSITA would have believed that Inokawa's convex lens, which concentrates light to a central detector, enhances light collection when Aizawa's sensor (and Dr. Kenny's illustrated combination) has peripheral detectors. Ex. 1003 ¶¶88-89. Instead, Dr. Kenny states that Aizawa would "include a convex protrusion that acts as a lens, as per Inokawa." Ex. 1003 ¶87. Dr. Kenny also states "a POSITA would have sought to incorporate a convex, lens structure as in Inokawa into Aizawa's acrylic plate to thereby increase light collection efficiency, in turn leading to more reliable pulse wave detection." Ex. 1003 ¶88. Dr. Kenny repeats that "Aizawa is modified to include a lens (right) as per Inokawa in order to 'increase the light-gathering ability.'" Ex. 1003 ¶89 (quoting from Inokawa, Ex. 1008 ¶15).

B. <u>Ground 1A Does Not Establish Obviousness</u>

1. <u>A POSITA Would Not Have Been Motivated To Combine Inokawa's Convex Lens With Aizawa's Sensor</u>

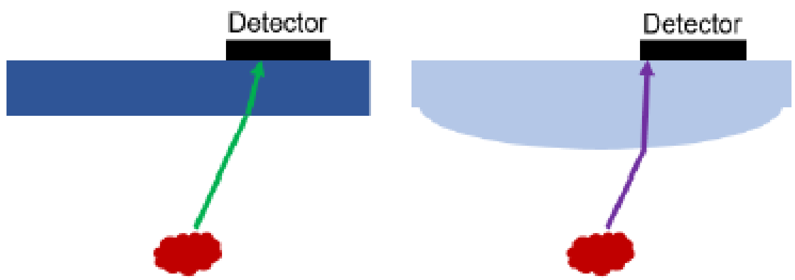
a) <u>Dr. Kenny and Petitioner Admit That Inokawa's Convex Lens Directs Light To The Center Of The Sensor</u>

48. Both Dr. Kenny and Petitioner agree that Inokawa's convex lens condenses light towards a centrally located detector—not periphery-located detectors like those used in Aizawa, as demonstrated by their admissions in this proceeding and their submissions in an IPR (IPR2020-01520 (Ex. 2019; Ex. 2020)) of related patent U.S. Pat. No. 10,258,265 (Ex. 2025). U.S. Pat. No. 10,258,265 and the '266 Patent share a common specification. U.S. Pat. No. 10,258,265 is at least a

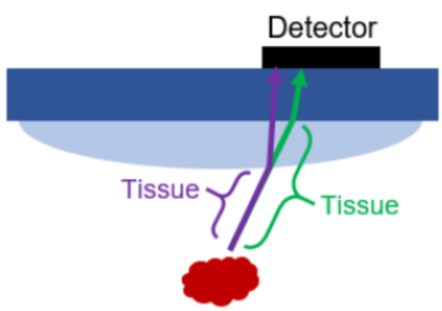
continuation of U.S. Patent App. No. 14/981290. The '266 Patent is also at least a continuation of U.S. Patent App. No. 14/981290.

49. Petitioner included the illustrations below in its Petition in this proceeding when discussing claim 6 of the '266 Patent, as well as its Petition in IPR2020-01520 when discussing claim 12 of U.S. Pat. No. 10,258,265. Pet. 34; Ex. 2019 at 45. Petitioner explained that "the lens of Inokawa, which is used to modify Aizawa ... serves a condensing function and thus, as with any other lens, refracts light passing through it." Pet. 34; Ex. 2019 at 44. Petitioner explained the drawing below as comparing "the length of non-refracted light (*i.e.*, without a lens, left) bouncing off an artery with that of refracted light (*i.e.*, with a lens, right)." Pet. 34; Ex. 2019 at 44-45. Refraction is a phenomenon related to the velocity of light in different materials because the velocity of light depends on the material through which it is traveling. Thus, the change in velocity as light moves from one material to another material may cause the light to deviate from its original direction, which is called "refraction." I note that the illustration below shows refraction for both the flat and convex surfaces because in both instances the illustrated light ray changes direction. Moreover, I note that, as illustrated by Petitioner, the change of direction for the light ray hitting the convex surface is relatively more towards the center of the cover than for the flat cover. Petitioner states that the result of the greater refraction of light with the convex cover with a protruding surface is that "the mean

path length of light traveling to the at least four detectors is reduced—that is, the purple line is shorter than the green line." Pet. 34; *see also* Ex. 2019 at 45. Petitioner also includes a drawing superimposing the two drawings below to "clearly show[] the shortened path traveled by refracted light in the presence of a lens, both within the tissue as well as for total path length." Pet. 34; Ex. 2019 at 45.



Petitioner's illustration of redirection of the mean path length of light traveling to the detectors when passing through a flat (left) and convex (right) cover (Pet. 34; *see also* Ex. 2019 at 45)



Petitioner's illustration superimposing the above refractions when illustrating how a convex surface a protruding surface changes the mean path length of incoming light (Pet. 35; *see also* Ex. 2019 at 45, 91)

50. Dr. Kenny also included and explained the two figures above in his declarations in this proceeding and IPR2020-01520 (Ex. 2020) as a way to illustrate the mean path length of light. Ex. 1003 ¶¶102-103; Ex. 2020 at 69-70. Dr. Kenny

explained that, when using a protruding surface such as Inokawa's convex lens, "the incoming light is 'condensed' toward the center." Ex. 1003 ¶102; Ex. 2020 at 69-70. Dr. Kenny goes on to explain: "Laying these two drawings on top of each other…the shortened path length within the tissue for the purple (refracted) line can be clearly seen compared to the path length within the tissue of the green (non-refracted) line." Ex. 1003 ¶103; Ex. 2020 at 70-71.

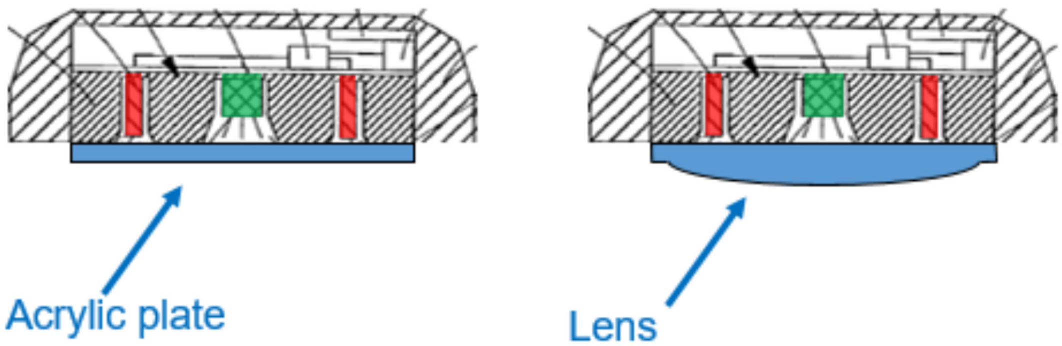
51. The understanding expressed by Petitioner and Dr. Kenny about condensing light is consistent with Inokawa's disclosure, which uses a convex surface as a way to increase the light gathering capability for a centrally located detector. Ex. 1008 ¶[0058], Fig. 2. As shown in Figure 2 (below), Inokawa illustrates how a protruding surface placed between the sensor and the skin condenses incoming light towards the central detector 25. Ex. 1008 ¶[0058], Fig. 2. This is helpful for Inokawa's particular sensor configuration because the emitters are located on the edges of the sensor while the detector is located in the center of the sensor. Thus, for Inokawa's particular linear arrangement of emitter-sensor-emitter, the protruding shape is reported to increase the light gathering capabilities of the centrally located detector when collecting the light emitted by the periphery-located LEDs and reflected by the measurement site. Ex. 1008 ¶[0058], Fig. 2. Inokawa illustrates this by using arrows that illustrate the general path of light from emitters, to the measurement site, and then back towards the central detector.

peripheral location (i.e., than if no protruding surface was present) to a more central location as a result of passing through the protruding surface. Ex. 1001 Fig. 14B.

55. Thus, as discussed, Petitioner, Dr. Kenny, and the ’266 Patent all support that a POSITA would have understood that the protruding surface illustrated by Inokawa would direct incoming light towards the center of the sensor. I also agree that a POSITA reading Inokawa would have understood that the protruding surface illustrated by Inokawa would direct incoming light towards the center of the sensor.

b) A POSITA Would Not Have Been Motivated To Direct Light Away From Aizawa’s Detectors And Would Have No Reasonable Expectation Of Success When Doing So

56. Although Petitioner and Dr. Kenny both agree that a POSITA would have understood that a protruding surface would converge incoming light toward the center, I understand that Petitioner asserts that a POSITA would place Inokawa’s convex lens on the sensor of Aizawa, which has the opposite configuration of components as compared to Inokawa, with peripheral detectors and a central emitter. Petitioner illustrates the result of this change in Aizawa as a device with the emitter (green) in the center and the detectors (red) on the periphery.



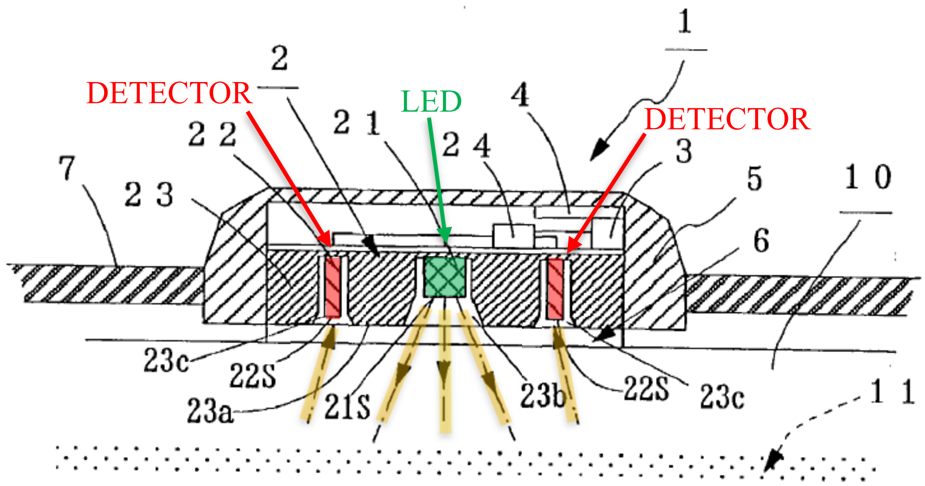
Petitioner's and Dr. Kenny's illustrations (Pet. 28; Ex. 1003 ¶89)
Aizawa's flat surface (left) versus Ground 1A's Proposed Combination (right)
The detectors are red and the emitter is green.

57. Dr. Kenny illustrates this same combination in his declaration. Ex. 1003 ¶89. Dr. Kenny states that "by positioning a lens above the optical components of Aizawa, as shown below, the modified cover will allow more light to be gathered and refracted toward the light receiving cavities of Aizawa, thereby further increasing the light-gathering ability of Aizawa beyond what is achieved through the tapered cavities." Ex. 1003 ¶89. As shown in Inokawa, as well as Dr. Kenny's other figures in his declaration and the '266 Patent, however, a POSITA would not have believed that the illustrated protruding surface would have allowed "more light to be gathered and refracted toward" Aizawa's peripheral detectors. Instead, as discussed above, a POSITA reading Inokawa would have expected more light would be gathered and refracted towards the center of the sensor, which is where Aizawa positions its single emitter.

58. Like Dr. Kenny, Petitioner asserts that a POSITA would have been motivated to "further Aizawa's objective of enhancing its light-collection efficiency." Pet. 27-28. But, again, a POSITA would not have expected Inokawa's protruding surface to accomplish this goal because, as discussed, a POSITA would have understood that a protruding surface directs light away from the periphery-located detectors. Ex. 1008 ¶[0058], Fig. 2. Thus, in view of Inokawa's teachings of increased light gathering to its central detector, a POSITA would have believed that a protruding surface would have undesirably decreased light-collection efficiency at Aizawa's peripheral detectors and reduced the measured optical signal. Ex. 1008 ¶[0058], Fig. 2.

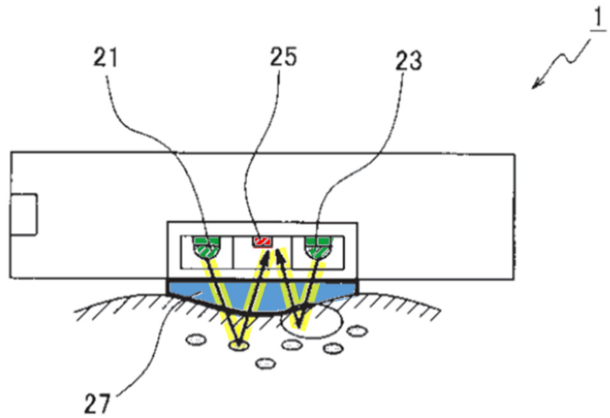
59. As illustrated in Aizawa, light is emitted from a central emitter (e.g., a light emitting diode or "LED") and reaches detectors (e.g., photodetectors) that are disposed around the emitter. Ex. 1006 ¶[0009]. The light emitted from the center-located emitter reflects from the artery of the wrist of the user and travels to the periphery located detectors. Ex. 1006 ¶¶[0009], [0027], [0036]. Thus, as illustrated in Aizawa Figure 1B, the light reaching Aizawa's detectors must travel in the opposite direction compared to the light in Inokawa. Ex. 1006 Fig. 1B. Aizawa states that its detectors "are disposed around the light emitting diode 21 on a circle concentric to the light emitting diode 21 in this embodiment." Ex. 1006 ¶[0027]. Aizawa contrasts its circular arrangement of detectors around an emitter with the

type of linear arrangement illustrated in Inokawa, explaining the photodetectors "should not be disposed linearly." Ex. 1006 ¶[0027]; *see also* ¶¶[0009], [0036]. Aizawa illustrates the light path as leaving a single centrally located emitter, passing through the body, and reflecting back to periphery-located detectors:



Aizawa Fig. 1B (cross-sectional view, color added)

60. As shown below, Inokawa illustrates the opposite emitter/detector arrangement and the opposite required light path for detection: light leaves periphery-located emitters, passes through the body, reflects back, and is focused on a single centrally located detector. Ex. 1008 ¶[0058], Fig. 2.



Inokawa's Features

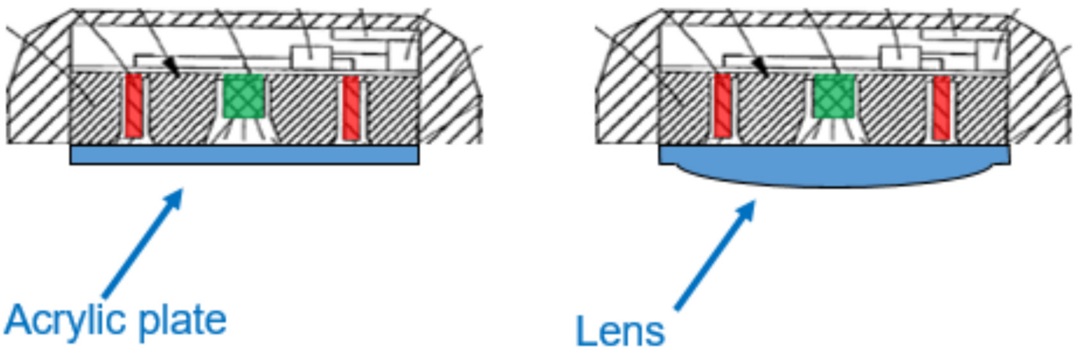
- **Green**: peripheral emitters (21, 23)
- **Red**: central detector (25)
- **Blue**: convex lens (27)
- Arrows showing direction of light in original, highlighted in yellow

Inokawa Fig. 2 (color added)

61. In my opinion, a POSITA would have linked the benefit of increased light gathering described in Inokawa to the arrangement of peripheral emitters and center-located detector, and thus would have believed that the benefit of increased light gathering resulting from Inokawa's protruding surface made sense in view of Inokawa's configuration using a centrally located detector. Ex. 1008 ¶[0058], Fig. 2. In contrast, a POSITA would have understood that Inokawa's protruding surface would not be suitable for achieving a goal of improved light gathering in Aizawa's sensor, because Aizawa uses a circular arrangement of peripheral detectors arranged around a central emitter and contrasts its approach to a linear detector/emitter arrangement. Ex. 1006 ¶¶[0009], [0027], [0036], Fig. 1B; *see also* Figs. 1A, 2, 4, 5.

62. As shown in the structure that Dr. Kenny and Petitioner assert would have resulted from the proposed combination of Inokawa and Aizawa (reproduced below), the result of the proposed combination places the emitter at the very center

of the protruding surface, which is the position at which the returning light would be concentrated.

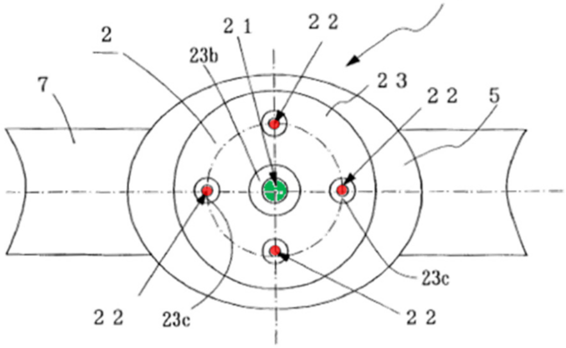


Petitioner's and Dr. Kenny's illustrations (Pet. 28; Ex. 1003 ¶89)
Aizawa's flat surface (left) versus Ground 1A's Proposed Combination (right)

63. In my opinion, a POSITA would have found this combination of a protruding surface with Aizawa's sensor particularly problematic because—consistent with Aizawa—the combination includes small detectors with small openings surrounded by a large amount of opaque material. Pet. 28; Ex. 1003 ¶89; Ex. 1006 Fig. 1B; *see also* Figs. 1A, 2, 4A-4B, 5. Aizawa's top-down view shown in Figure 1A confirms the detectors' small size. Ex. 1006 Fig. 1A; *see also* Figs. 2, 4A-4B. Aizawa Figure 1A is reproduced below with the detectors highlighted in red and the emitters highlighted in green. Aizawa explains that the openings of the detector cavities (23c in the figure below) are larger than the size of the photodetector itself, and intended to "expand…the light receiving areas of the

photodetectors… [and] are tapered such that their widths increase toward the contact face.” Ex. 1006 ¶[0024].

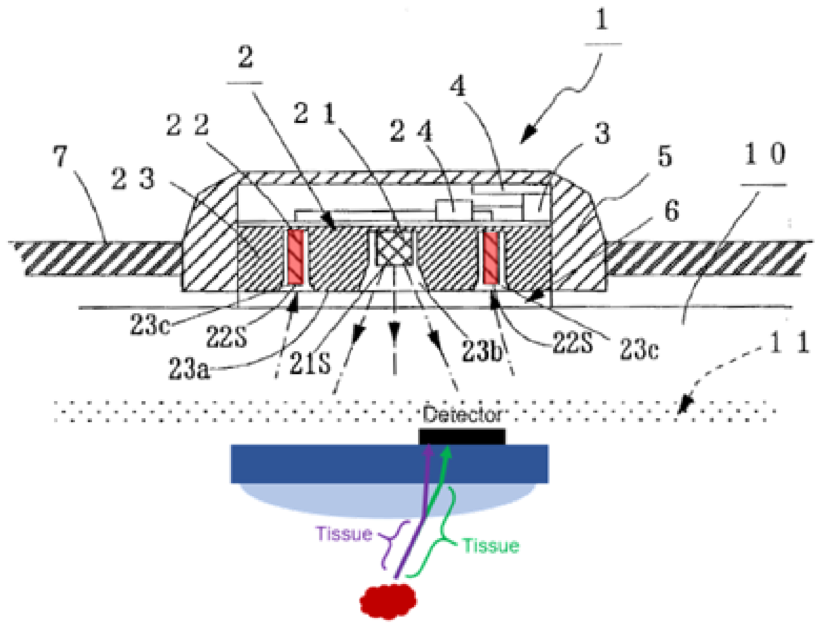
FIG. 1 (a)



Aizawa’s Features

- **Green**: central emitter (21)
- **Red**: peripheral detector (22)

64. When discussing the change in light path for light interacting with a convex surface, Dr. Kenny’s declaration does not use either Aizawa’s structure or what Dr. Kenny asserts would have been the result of combining Aizawa and Inokawa. Instead of using Aizawa’s actual structure (below, top), Dr. Kenny presents a separate figure (below, bottom) that drastically increases the size of a detector compared to Aizawa and eliminates the surrounding barriers.



Aizawa's figure illustrating detectors (22, red) (Ex. 1006 Fig. 1B)

Dr. Kenny's depiction drastically increasing size of Aizawa's detector (black) (Ex. 1003 ¶103)

65. Applying Dr. Kenny's illustration of the redirected light path (illustrated by the purple line in the second figure above) to Aizawa's actual detectors (highlighted in red in the first of the two figures above) confirms the redirected light would not even reach the detectors because it would miss both Aizawa's small detectors and even the slightly larger cavities due to passing through the convex surface. It appears that Dr. Kenny increased the size of Aizawa's detector approximately five-fold to so that the redirected light reached the detector, and also eliminated the opaque barrier of Aizawa's holder 23 entirely. There is no analysis or explanation of these changes in Dr. Kenny's declaration, or any acknowledgement that the redirection of light towards a more central location would have caused the redirected light to miss Aizawa's detectors entirely. *See* Ex. 1003 ¶¶102-103 (No

indication that size of Aizawa's detectors had to be changed in order to still detect light redirected by convex surface).

c) <u>Dr. Kenny's Testimony Further Undermines Obviousness</u>

66. Dr. Kenny's declaration includes figures that he describes as illustrating the phenomenon of how "the incoming light is 'condensed' toward the center," after interacting with a protruding surface. Ex. 1003 ¶¶102, 154; *see also* Ex. 2020 at 69-70. The term "condensing" in the context of light passing through a surface describes the general understanding of a POSITA that light is directed towards a more central location when passing through a protruding surface, and thus results in a relative increase of light at the center and decrease of light at the peripheral edge of underlying structure. I further note that the figures at paragraphs 102-103 in Dr. Kenny's declaration are used with respect to a limitation involving the "mean path length of light traveling to the at least four detectors." Ex. 1003 ¶¶103, 155; *see also* Ex. 2020 at 69-71, 115-117. In particular, the limitation Dr. Kenny analyzed in his declaration is: "The noninvasive optical physiological sensor of claim 4, wherein the lens is configured to reduce a mean path length of light traveling to the plurality of detectors." Further, in my opinion, as discussed above, a POSITA would have believed that the protruding surface in Inokawa would have redirected more light overall to the center of the sensor, resulting in relatively more light at the center of the sensor and relatively less light towards the periphery of the sensor.

data processing and not sensor design. Training in data processing would not have prepared a POSITA for the type of design process identified by Dr. Kenny as needed to develop a working optical physiological sensor.

74. A POSITA would have understood that Inokawa's convex lens benefits Inokawa's sensor design with its center-located detector. Ex. 1008 ¶58, Fig. 2. In my opinion, a POSITA would have credited the teaching of Inokawa itself, which shows that a protruding surface directs incoming light towards the center. Ex. 1008 ¶58, Fig. 2. In contrast, I do not believe a POSITA would have been motivated to go through Dr. Kenny's extensive trial and error process to try and figure out whether Inokawa's protruding surface would have analogous benefits in a device with peripheral detectors and a central emitter. Instead, a POSITA would have taken Inokawa's teaching at face value, consistent with the general understanding of how light interacts with a protruding surface.

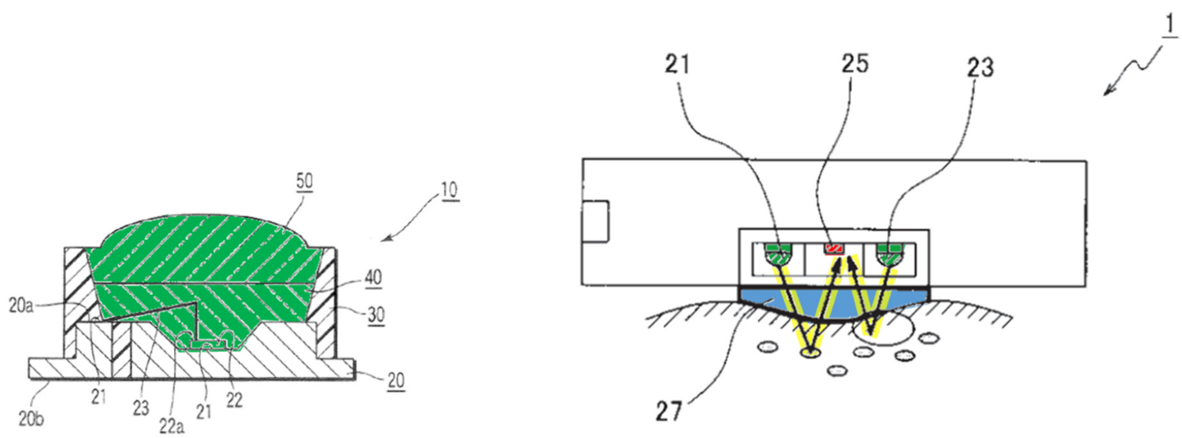
75. Thus, accounting for the possibility that a POSITA with no experience in optical physiological sensor design would nonetheless understand the wide ranging considerations identified by Dr. Kenny at his deposition in related IPRs, it is still my opinion that Inokawa does not establish a valid motivation to combine Inokawa with Aizawa, much less a reasonable expectation of success. When addressing a reasonable expectation of success, Dr. Kenny focuses his discussion on the manufacturing of a device, and not whether the device would be able to

successfully act as a physiological monitor or sensor. See, e.g., Ex. 1003 ¶¶90-91. Whether or not "the shape of the cover can be readily modified" (Ex. 1003 ¶90), Dr. Kenny never explains why a POSITA would have expected Petitioner's proposed combination to result in a successful optical physiological sensor. The lack of analysis is particularly important because a POSITA would have expected a protruding surface to decrease the optical signal at the peripheral detectors. The possibility that POSITA could manufacture a device is not evidence a POSITA would have reasonably expected the resulting device to successfully work as an optical physiological measurement device. Decreasing the amount of light reaching the detectors will decrease the signal, increase the relative amount of noise, and could thus result in a signal unusable for actually monitoring a physiological parameter.

d) **Petitioner's Obviousness Challenge Also Relies On References Not Identified As Part Of Ground 1A Without A Motivation To Combine Or Expectation Of Success**

76. I further note that the Petition, and Dr. Kenny's analysis, apparently relies on references that neither the Petitioner nor Dr. Kenny identifies as part of Ground 1A. The Petition states that Ground 1A includes only two references: Aizawa and Inokawa. Pet. 2. But Dr. Kenny's analysis also relies on another cited reference: Nishikawa. Ex. 1003 ¶¶86-91.

with curved surfaces similar to Nishikawa's LEDs are a fraction of the size of the sensor or cover. Ex. 1008 Fig. 2 (21, 23). Likewise, Aizawa similarly illustrates that the LED is a much smaller part of the overall sensor. Ex. 1006 Fig. 1; *see also* Figs. 4, 5. Thus, given the differences between Nishikawa on the one hand and Inokawa and Aizawa on the other hand, a POSITA would not have been motivated to apply Nishikawa's lens design in a physiological sensor and would have had no expectation of success in doing so.



Comparison of Nishikawa's LED package (left) & Inokawa's sensor Fig. 2 (right) showing scale difference (LED package highlighted in green in both)

2. <u>A POSITA Would Not Have Added A Second Emitter (LED) To Aizawa</u>

79. Even if a POSITA were motivated to combine Aizawa and Inokawa, the combination of Aizawa and Inokawa still would not result in the claimed invention because, in my opinion, it does not disclose all of the claim limitations. Every claim of the '266 Patent requires (1) a plurality of emitters and (2) at least four detectors. Ex. 1001 Claims 1 and 9. Neither Aizawa nor Inokawa includes both

a plurality of emitters and at least four detectors. *See, e.g.*, Ex. 1006 Fig. 1 (single center-located emitter with multiple peripheral detectors); Ex. 1008 Fig. 2 (two peripheral emitters with a single center-located detector). Neither Aizawa nor Inokawa disclose or suggest the use of both multiple detectors and multiple emitters in the same sensor.

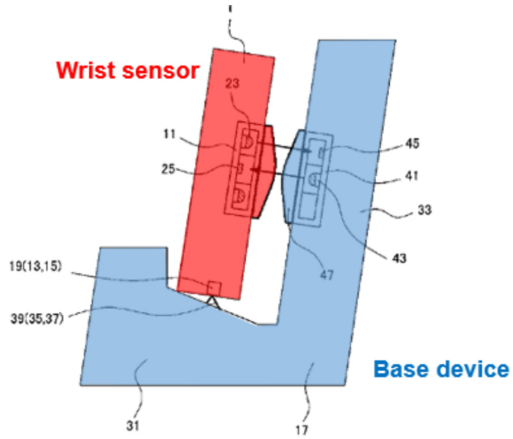
80. Aizawa has no disclosure of a sensor with multiple detectors and multiple emitters. To the extent Dr. Kenny suggests Aizawa teaches the use of multiple detectors and multiple emitters in a single sensor, I disagree. In one of Aizawa's embodiments, multiple detectors surround a single centrally located LED. Ex. 1006 ¶[0033], Figs. 1A-1B, 2, 4A-4B, 5. In this embodiment, Aizawa teaches the number of photodetectors "disposed around the light emitting diode" can be increased or decreased. Ex. 1006 ¶[0032]. In Aizawa's other embodiment, which is not illustrated, multiple LEDs surround a single centrally located detector. *See* Ex. 1006 ¶[0033] ("The same effect can be obtained when the number of photodetectors 22 is 1 and a plurality of light emitting diodes 21 are disposed around the photodetector 22."). Inokawa likewise discloses an arrangement where two LEDs are used on either side of a single detector. Ex. 1008 ¶[0058], Fig. 2. Neither reference discloses a sensor with multiple emitters used with multiple detectors.

81. Dr. Kenny does not address the teachings of his cited art that indicate a sensor with multiple emitters only has one detector; or conversely, in the case of

single photodiode."). There is no multi-detector/multi-emitter embodiment disclosed in either Aizawa or Inokawa, and no reason why a POSITA would have been motivated by these references to change both references to use a multi-detector/multi-emitter arrangement. Dr. Kenny asserts that "it was common practice in the pulse oximeter field to centrally locate multiple emitters of different wavelengths" (Ex. 1003 ¶80); this is irrelevant to Aizawa because Aizawa is not an oxygen saturation sensor, it is a pulse wave sensor (Ex. 1006 ¶[0002]).

84. Dr. Kenny points to two reasons why Inokawa would have motivated a POSITA to add a second LED to Aizawa. First, Dr. Kenny asserts that a POSITA would have added a second LED based on the "added ability to measure body movement." Ex. 1003 ¶72; *see also* ¶73. But Aizawa already includes this functionality, and explains that it provides a "device for computing the amount of motion load from the pulse rate." Ex. 1006 ¶[0015]. There is no need for a design change when Aizawa already includes the relevant functionality.

85. Second, Dr. Kenny asserts that adding a second LED would enable Aizawa to transmit data to a base device with a configuration like that in Inokawa. Ex. 1003 ¶76. Dr. Kenny asserts that "Aizawa contemplates uploading data from its wrist sensor to an external base device" and would have incorporated Inokawa's base device "that both charges and receives data from the pulse sensor." Ex. 1003 ¶76.



Dr. Kenny's Illustration of Inokawa's Base Device (Ex. 1003 ¶76)

86. But Aizawa already includes a transmitter in its structure, so Aizawa does not need to incorporate Inokawa's base-device data transmission approach. Ex. 1006 ¶¶[0023], [0028], [0035]. Moreover, Aizawa's goal is "real-time measuring" (Ex. 1006 ¶[0004]) with the transmitter "transmitting the measured pulse rate data to a display," (Ex. 1006 ¶[0015]). As Dr. Kenny acknowledged, Aizawa's sensor is designed for monitoring heart rate at the time of exercise. Ex. 2020 at 59. Inokawa's base device, however, only transmits pulse rate data "when the pulse sensor ... is mounted onto the base device." *See, e.g.*, Ex. 1008 Abstract. Inokawa's system thus requires the user to remove the monitoring device, thus stopping the monitoring, and attach it to a base solution before the sensor can transmit data. Ex. 1008 Figs. 3, 8. Transforming Aizawa into a base-device-transmitter eliminates the ability to take and display real-time measurements, one of Aizawa's stated goals, while increasing power consumption and cost by adding an additional LED. Ex. 1008 ¶[0033].

101. Dr. Kenny thus explains the motivation for the proposed combination is: "a POSITA would have been motivated to incorporate the lens of Inokawa into to [sic] cover of Mendelson-1988 in order to increase the light collection efficiency." Ex. 1003 ¶137. Dr. Kenny also asserts that the proposed combination modifies Mendelson-1988's flat epoxy cover with "a curved one as per Inokawa." Ex. 1003 ¶138. Dr. Kenny asserts that "The lens of Inokawa provides precisely this benefit to Mendelson'1988's device by providing a protective cover that further refracts and concentrates the incoming light beams to thereby enhance the light collection efficiency and, by extension, the signal to noise ratio." Ex. 1003 ¶137.

102. As discussed in more detail below, I disagree that a POSITA would have believed that Inokawa's protruding surface would have increased the amount of light reaching Mendelson-1988's peripheral detectors. Likewise, I disagree that a POSITA would have understood that the "lens of Inokawa provides precisely this benefit to Mendelson[-]1988's device" of increasing light collection efficiency and maximizing the detected signals, as Dr. Kenny asserts (Ex. 1003 ¶137).

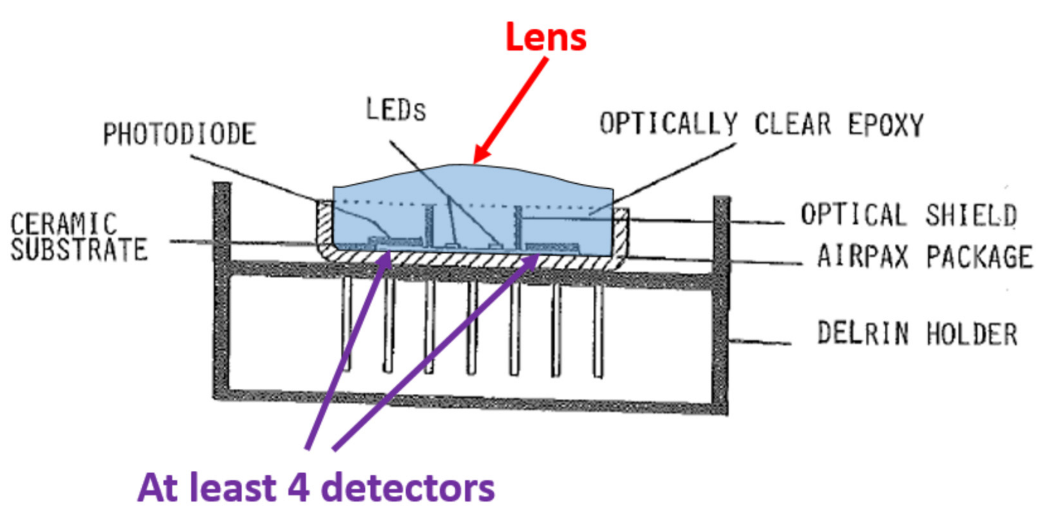
B. <u>Ground 2 Does Not Establish Obviousness</u>

1. <u>Ground 2 Does Not Demonstrate A Motivation To Combine Mendelson-1988 And Inokawa, And Does Not Establish A Reasonable Expectation Of Success</u>

103. The proposed combination of Mendelson-1988 and Inokawa suffers from the same problems as the proposed combination of Aizawa and Inokawa. In

the proposed Mendelson-1988-Inokawa combination, as in the proposed Aizawa-Inokawa combination, the detectors are on the periphery of the device. Ex. 1015 at 2, Figs. 2A-2B. As explained above, Inokawa's convex lens focuses light on a centrally located detector. *See* ¶¶42-61 and 66-75 of this declaration, above; *see also* Ex. 2020 at 115-117 (Dr. Kenny explaining that light passing through a convex surface is condensed towards the center relative to a flat surface). A POSITA would not have been motivated to incorporate a protruding surface to direct light away from the detectors for the same reasons discussed above. *See* ¶¶42-61 and 66-75 of this declaration, above.

104. As shown in Dr. Kenny's illustration below, the proposed combination of Mendelson-1988 and Inokawa positions detectors (Mendelson-1988's photodiodes) on the periphery of the sensor:



Dr. Kenny's illustration of the proposed combination
of Mendelson-1988 and Inokawa (Ex. 1003 ¶139)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent of:	Poeze, et al.	
U.S. Patent No.:	10,376,191	Attorney Docket No.: 50095-0011IP1
Issue Date:	August 13, 2019	
Appl. Serial No.:	16/409,515	
Filing Date:	May 10, 2019	
Title:	MULTI-STREAM DATA COLLECTION SYSTEM FOR NONINVASIVE MEASUREMENT OF BLOOD CONSTITUENTS	

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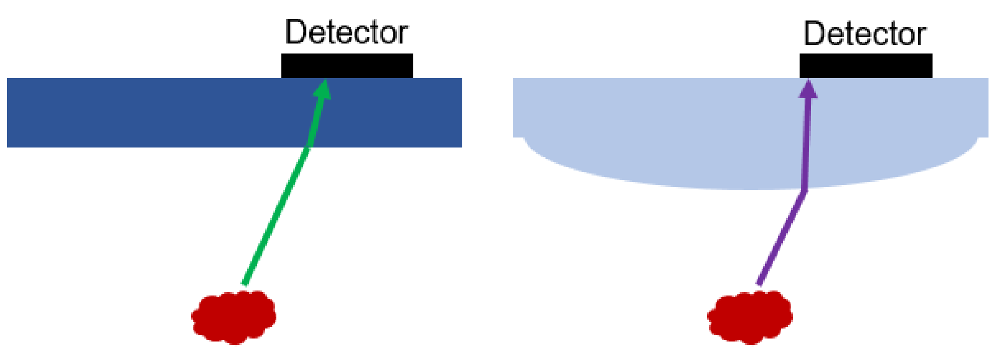
P.O. Box 1450
Alexandria, VA 22313-1450

PETITION FOR *INTER PARTES* REVIEW OF UNITED STATES PATENT NO. 10,376,191 PURSUANT TO 35 U.S.C. §§ 311–319, 37 C.F.R. § 42

Claim 6

[6]: "The noninvasive optical physiological sensor of claim 4, wherein the lens is configured to reduce a mean path length of light traveling to the plurality of detectors."

A POSITA would have recognized that such feature is rendered obvious by Aizawa-Inokawa. APPLE-1003, ¶¶101-103. For example, the lens of Inokawa, which is used to modify Aizawa as explained in Section III.A.3(a), serves a condensing function and thus, as with any other lens, refracts light passing through it. APPLE-1008, [0015], [0058]; APPLE-1003, ¶101. Thus, referring to the drawing below which compares the length of non-refracted light (*i.e.*, without a lens, left) bouncing off an artery with that of refracted light (*i.e.*, with a lens, right), it can be seen that the mean path length of light traveling to the at least four detectors is reduced—that is, the purple line is shorter than the green line. APPLE-1003, ¶102. This holds true for both the total length travelled as well as length travelled/attenuated through skin. *Id.*



APPLE-1003, ¶102.

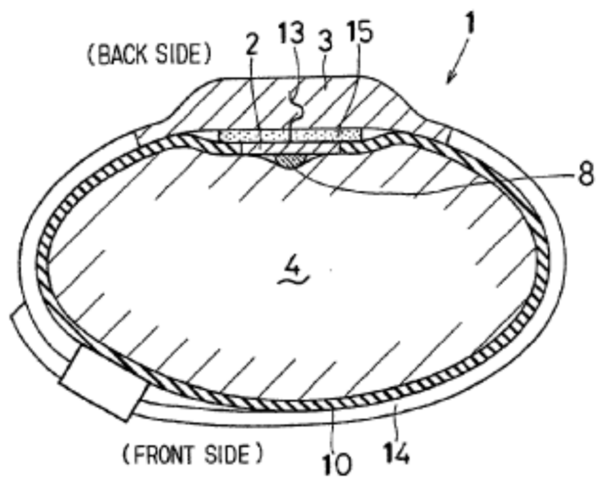
APPLE-1008, [0015], [0058]; APPLE-1003, ¶124. Moreover, because the lens acts as a light concentrator that improves the light-gathering ability of the modified device, the modified cover is a window that further provides a light concentrating function. *Id.*

B. [GROUND 1B] – Claims 1-6, 8-16, 18, and 19 are rendered obvious by Aizawa in view of Inokawa and Ohsaki

1. Overview of Ohsaki

Ohsaki is generally directed to "[a] pulse wave sensor includes a detecting element and a sensor body" where "[t]he pulse wave sensor is worn on the back side of a user's wrist." APPLE-1014, Abstract. As seen below, the pulse sensor of Ohsaki is "worn on the back side of the user's wrist 4...in the similar manner as a wristwatch is normally worn," *Id.*, [0016]; APPLE-1003, ¶¶63-64.

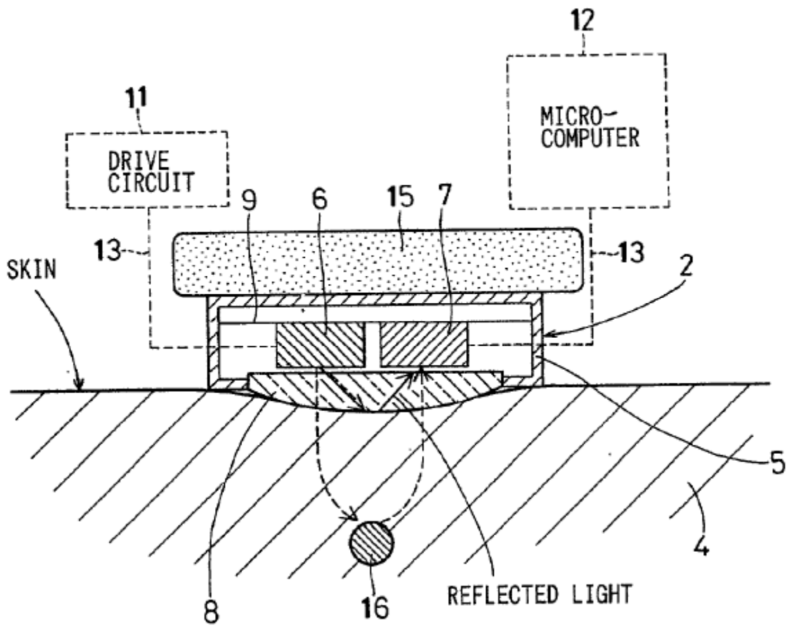
FIG. 1



APPLE-1014, FIG. 1.

Referring to FIG. 2 below, Ohsaki can sense pulse by emitting light through a light emitting element 6 and detecting reflected light using a light receiving element 7. APPLE-1014, [0017]. Ohsaki also provides a translucent board 8 that is transparent to light and includes a convex surface "in intimate contact with the surface of the user's skin." *Id.*, [0009], [0017].

FIG. 2



APPLE-1014, FIG. 2; APPLE-1003, ¶¶125-127.

2. Analysis

As described above in Ground 1A and Section III.A.3(a), a POSITA would have sought to incorporate an Inokawa-like lens into the cover of Aizawa to in-

crease the light collection efficiency. Here, Ohsaki provides an additional motivation and rationale for a POSITA to modify Aizawa to include a "lens" as per element [1d]. APPLE-1003, ¶¶128-129.

For example, Ohsaki teaches that adding a convex surface to a flat cover (*i.e.*, translucent board 8) can help prevent the device from slipping on the tissue when compared to a flat cover. APPLE-1014, [0025]; APPLE-1003, ¶128. In this context, Aizawa similarly seeks to prevent slippage between the device and the user's wrist—and pursues this objective by pressing its cover (*i.e.*, acrylic transparent plate 6) and trying to improve "adhesion between the wrist 10 and the pulse rate detector 11." APPLE-1006, [0026], [0030].

A POSITA reviewing Aizawa and Ohsaki would have recognized Ohsaki's use of a convex protrusion in its cover as a desirable configuration that would help to further prevent slippage of Aizawa's device. APPLE-1003, ¶128. Thus, a POSITA wanting to achieve improved adhesion between the detector and the skin, as expressly recognized in Aizawa, would have readily modified Aizawa's cover to have a convex protrusion as per Ohsaki. *Id*.

The resulting combination would have provided all remaining elements of claims 1-6, 8-16, 18, and 19 in the same manner as previously described in Ground 1A; APPLE-1003, ¶129.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APPLE, INC.,
Petitioner,

v.

MASIMO CORPORATION,
Patent Owner.

Case IPR2021-00209
Patent 10,376,191

PETITIONER'S EXHIBIT LIST

EXHIBITS

APPLE-1001	U.S. Patent No. 10,376,191 to Poeze, et al. ("the '191 patent")
APPLE-1002	Excerpts from the Prosecution History of the '191 patent ("the Prosecution History")
APPLE-1003	Declaration of Dr. Thomas W. Kenny
APPLE-1004	Curriculum Vitae of Dr. Thomas W. Kenny
APPLE-1005	*Masimo Corporation, et al. v. Apple Inc.,* Complaint, Civil Action No. 8:20-cv-00048 (C.D. Cal.)
APPLE-1006	U.S. Pub. No. 2002/0188210 ("Aizawa")
APPLE-1007	JP 2006-296564 ("Inokawa")
APPLE-1008	Certified English Translation of Inokawa and Translator's Declaration
APPLE-1009	U.S. Pat. No. 7,088,040 ("Ducharme")
APPLE-1010	U.S. Pat. No. 8,177,720 ("Nanba")
APPLE-1011 to 1013	RESERVED
APPLE-1014	U.S. Pub. No. 2001/0056243 ("Ohsaki")
APPLE-1015	"Design and Evaluation of a New Reflectance Pulse Oximeter Sensor," Y. Mendelson, et al.; Worcester Polytechnic Institute, Biomedical Engineering Program, Worcester, MA 01609; Association for the Advancement of Medical Instrumentation, vol. 22, No. 4, 1988; pp. 167-173 ("Mendelson-1988")
APPLE-1016	RESERVED
APPLE-1017	RESERVED
APPLE-1018	"Acrylic: Strong, stiff, clear plastic available in a variety of brilliant colors," available at https://www.curbellplastics.com/Research-Solutions/Materials/Acrylic
APPLE-1019 to 1022	RESERVED
APPLE-1023	U.S. Pat. App. Pub. No. 2007/0145255 ("Nishikawa")

APPLE-1024	"Measurement Site and Photodetector Size Considerations in Optimizing Power Consumption of a Wearable Reflectance Pulse Oximeter," Y. Mendelson, et al.; Proceedings of the 25th IEEE EMBS Annual International Conference, 2003; pp. 3016-3019 ("Mendelson-2003")
APPLE-1025	U.S. Pat. No. 6,801,799 ("Mendelson-'799")
APPLE-1026	Declaration of Jacob Munford
APPLE-1027 to 1036	RESERVED
APPLE-1037	*Masimo Corporation, et al. v. Apple Inc.*, Second Amended Complaint, Civil Action No. 8:20-cv-00048 (C.D. Cal.) (Redacted)
APPLE-1038	U.S. Patent No. 8,577,431 to Lamego et al. ("CIP Patent")
APPLE-1039	Order Re Motion to Stay in *Masimo Corporation et al. v. Apple Inc.*, Case 8:20-cv-00048-JVS-JDE, October 13, 2020

Filed July 27, 2022

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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MASIMO CORPORATION,
Patent Owner.

IPR2021-00209
Patent 10,376,191

PATENT OWNER'S NOTICE OF APPEAL TO THE U.S. COURT OF APPEALS FOR THE FEDERAL CIRCUIT

Pursuant to 28 U.S.C. § 1295(a)(4)(A), 35 U.S.C. §§ 141(c), 142, and 319, 37 C.F.R. §§ 90.2(a) and 90.3, and Rule 4(a) of the Federal Rules of Appellate Procedure, Patent Owner Masimo Corporation ("Masimo") hereby appeals to the United States Court of Appeals for the Federal Circuit from the Judgment – Final Written Decision (Paper 32) entered on May 25, 2022 (Attachment A) and from all underlying orders, decisions, rulings, and opinions that are adverse to Masimo related thereto and included therein, including those within the Decision Granting Institution of *Inter Partes* Review, entered June 3, 2021 (Paper 7). Masimo appeals the Patent Trial and Appeal Board's determination that claims 1-6, 8-16, 18 and 19 of U.S. Patent 10,376,191 are unpatentable, and all other findings and determinations, including but not limited to claim construction, as well as all other issues decided adverse to Masimo's position or as to which Masimo is dissatisfied in IPR2021-00209 involving Patent 10,376,191.

Masimo is concurrently providing true and correct copies of this Notice of Appeal, along with the required fees, to the Director of the United States Patent and Trademark Office and the Clerk of the United States Court of Appeals for the Federal Circuit.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: July 27, 2022

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DocCode – SCORE

SCORE Placeholder Sheet for IFW Content

Application Number: 16409515 Document Date: 05/10/2019

The presence of this form in the IFW record indicates that the following document type was received in electronic format on the date identified above. This content is stored in the SCORE database.

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- USPTO employees may access SCORE content via DAV or via the SCORE web page.
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Form Revision Date: March 1, 2019

DETAILED ACTION

1. Claims 2-20 are allowed.

2. The following is an examiner's statement of reasons for allowance: The terminal disclaimer to USPNs 8,437,825; 10,299,708; 10,292,628; and 10,258,266 has been approved on 06/12/2019 to resolve the double patenting issue(s). Schulz et al. (USPN 7,341,559 – applicant cited) teaches a noninvasive optical physiological sensor (Figs. 1-4 and 19 and associated descriptions) comprising: an emitter configured to emit light into tissue of a user (element 400, Figs. 1-4 and 19 and associated descriptions); a detector configured to detect light that has been transmitted through the tissue of the user (elements 800 and 802, Figs. 1, 4, 8, and 19 and associated descriptions); a housing configured to house the detector (Figs. 1-4 and 19 and associated descriptions); and a lens configured to be located between the tissue of the user and the plurality of detectors when the noninvasive optical physiological sensor is proximate the tissue of the user, wherein the lens comprises a single outwardly protruding convex surface (element 1921A and 1920A, Fig. 19B and associated descriptions). Chaiken et al. (USPN 6,223,063 – applicant cited) teaches an optical physiological measurement sensor (Figs. 1-9 and associated descriptions) comprising: a laser configured to emit light into tissue of a user (element 130, Figs. 1-2 and associated descriptions); a circular housing including a planar surface (elements 110 and 140, Figs. 1-2 and associated descriptions); at least four detectors arranged on the planar surface of the circular housing (elements 160, Figs. 1-2 and associated descriptions), wherein the four detectors are arranged in a grid pattern (Figs. 1-2 and associated descriptions); and a

lens (element 110, Figs. 1-7 and associated descriptions), wherein at least a portion of the lens protrudes from the housing (elements 150, Figs. 1-3 and associated descriptions). Mannheimer et al. (USPN 5,099,842 – applicant cited) teaches a noninvasive optical physiological sensor (Figs. 1-5 and associated descriptions) comprising: a plurality of emitters configured to emit light into tissue of a user (three LEDs in element 120, Figs. 1 and associated descriptions); a detector (element 120, Figs. 1-3 and associated descriptions) configured to detect light that has been transmitted through the tissue of the user; a housing configured to house the detector (Figs. 1-3 and associated descriptions); and light transmissive bumps (elements 100, Figs. 1-3 and associated descriptions) configured to be located between the tissue of the user and the plurality of detectors when the noninvasive optical physiological sensor is proximate the tissue of the user (Figs. 1-3 and associated descriptions). Wong et al. (USPN 5,601,079 – applicant cited) teaches a noninvasive optical physiological measurement device (Figs. 4-8 and associated descriptions) comprises a plurality of emitters; a housing configured to house at least the plurality of detectors in a circular portion of the housing (see Figs. 4-8 and associated descriptions). However, the prior art of record does not teach or suggest "*a plurality of detectors configured to detect light that has been attenuated by tissue of the user, wherein the plurality of detectors comprise at least four detectors;… and a lens configured to be located between the tissue of the user and the plurality of detectors when the noninvasive optical physiological sensor is worn by the user, wherein the lens comprises a single outwardly protruding convex surface*" or "*a housing including a planar surface; at least four detectors arranged on the planar surface of the housing, wherein the four detectors are*

arranged in a grid pattern; and a lens forming a cover of the housing, wherein at least a portion of the lens protrudes from the housing and the lens comprises a single convex surface", in combination with the other claimed elements/ steps.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHU CHUAN LIU whose telephone number is (571)270-5507. The examiner can normally be reached on M-Th (8am-6pm).

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jacqueline Cheng can be reached on (571) 272-5596. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent of:	Poeze et al.	
U.S. Patent No.:	10,376,191	Attorney Docket No.: 50095-0011IP1
Issue Date:	August 13, 2019	
Appl. Serial No.:	16/409,515	
Filing Date:	May 10, 2019	
Title:	MULTI-STREAM DATA COLLECTION SYSTEM FOR NONINVASIVE MEASUREMENT OF BLOOD CONSTITUENTS	

DECLARATION OF DR. THOMAS W. KENNY

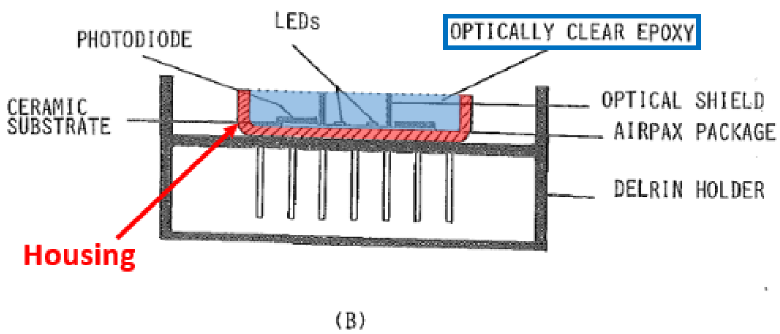
Declaration

I declare that all statements made herein on my own knowledge are true and that all statements made on information and belief are believed to be true, and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable under Section 1001 of Title 18 of the United States Code.

By: ______________________________

Thomas W. Kenny, Ph.D.

67. In more detail, the sensor of Mendelson-1988, shown below, includes a housing (colored red) that encases the optical components as well as an optically clear adhesive/epoxy (colored blue) that encapsulates such components within the housing and, thus, acts as a light permeable cover for the detectors. APPLE-1015, 168.



APPLE-1015, FIG. 2(b)

VIII. GROUND 1A – Claims 1-6, 8-16, 18, and 19 Are Rendered Obvious by Aizawa in view of Inokawa

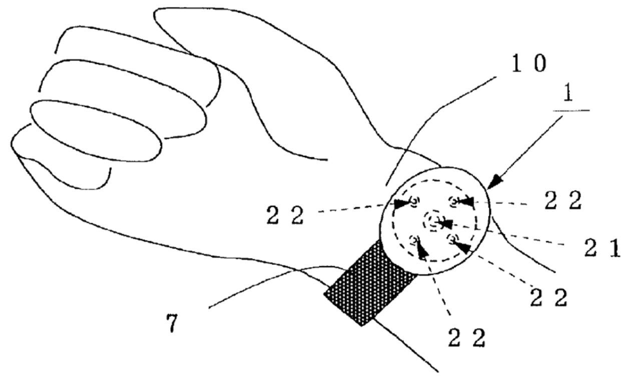
A. Claim 1

[1pre] A noninvasive optical physiological sensor comprising:

68. Aizawa discloses a pulse sensor that is designed to "detect[] the pulse wave of a subject from light reflected from a red corpuscle in the artery of a wrist of the subject by irradiating the artery of the wrist." APPLE-1006, [0002]. Thus, the sensor of Aizawa is a noninvasive optical physiological sensor and provides an indication of a physiological parameter, namely pulse. *Id.* As shown below,

Aizawa's sensor is adapted to be worn by the user by being attached to the user's wrist. *Id.*, [0026].

F I G. 2



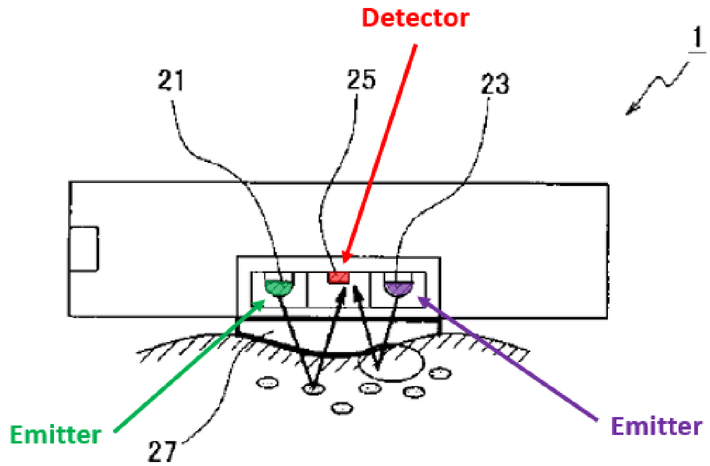
APPLE-1006, FIG. 2

[1a] a plurality of emitters configured to emit light into tissue of a user;

69. As noted above, Aizawa teaches a pulse wave sensor having multiple detectors disposed circularly around an emitter. APPLE-1006, [0023]. As also noted, Aizawa considers the use of multiple emitters but does not expressly talk about using multiple emitters with multiple detectors. *Id.*, [0033].

70. Here, I note that Inokawa teaches the use of two different types of emitters "such as an infrared LED or a green LED" and further teaches that "work can be divided between the various means, with an infrared LED used to detect vital signs and transmit vital sign information, and a green LED used to detect pulse." APPLE-1008, [0014], [0044], [0058], [0059]. As shown below, Inokawa teaches

use of a first emitter (LED 21, colored green) and a second emitter (LED 23, colored purple). *Id.*, [0058], [0059].

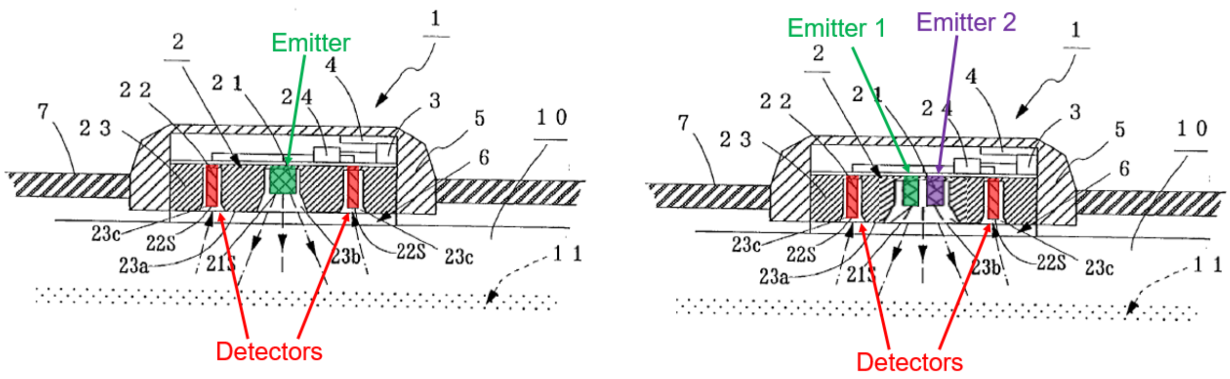


APPLE-1008, FIG. 2

71. A POSITA in possession of both Aizawa and Inokawa would have realized that Inokawa's teachings concerning the use of two different emitters operating at different wavelengths would be applicable to Aizawa as well to yield similar benefits. For example, Aizawa only mentions using a single wavelength of light, but Inokawa teaches the benefits of dividing the role of a single LED into two different LEDs "with an infrared LED used to detect vital signs and transmit vital sign information, and a green LED used to detect pulse." APPLE-1008, [0014], [0044], [0058], [0059].

72. Thus, a POSITA would have recognized that providing an additional emitter of a different wavelength to Aizawa, as per Inokawa, would enable Aizawa's device to, for instance, (1) use the existing infrared LED to detect body motion and

(2) use the added green LED to detect pulse. *Id.*, [0059]. While it's possible that adding more emitters to Aizawa may lead to increased power consumption, a POSITA seeking to improve detection performance would have nevertheless looked to Inokawa's multi-emitter setup to achieve enhanced performance benefits. *Id.* Indeed, various other prior art pulse sensing devices teach, similar to Inokawa, using a first LED emitting at below 600 nm (*e.g.*, green) to measure blood flow and a second LED emitting at above 600 nm (*e.g.*, infrared) to measure body movement. *See, e.g.,* APPLE-1010, 8:45-50. The added ability to measure body movement in this manner will allow for a more reliable measurement that can, for instance, take into account and correct for inaccurate readings related to body movement. *Id.* For instance, the signal component corresponding to body movement can be subtracted from the pulse signal to help better isolate the desired pulse data. *Id.* Thus, applying the teachings of Inokawa, a POSITA would have been motivated and found it obvious to divide the single emitter of Aizawa, into two emitters operating at two different wavelengths, as demonstrated below, to be able to detect both pulse and body movement signals.



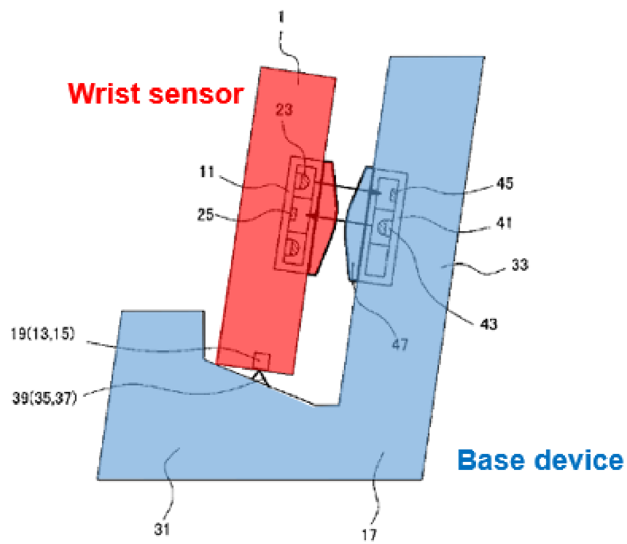
APPLE-1006, FIG. 1(b)

73. More specifically, one of ordinary skill would have replaced Aizawa's LED 21 with two LEDs, each emitting a different wavelength. As suggested by Inokawa, one of ordinary skill would have recognized that this would improve Aizawa's sensor by enabling it to account for motion load through use of the second LED, by detecting and recording body motion in addition to blood flow. APPLE-1008, [0006], [0028], [0035]. Because, Aizawa already contemplates adding additional emitters, a POSITA would have known how to make the changes needed, for example concerning circuitry, to add another LED in this manner. APPLE-1006, [0032]. While the exemplary drawings I've provided above show two smaller emitters replacing a larger emitter, which is simply a matter of design choice to a POSITA in circuit design and assembly, a similar effect could be achieved by simply enlarging the emitter cavity and including two larger emitters, which is again a simple matter of design choice.

74. Such a modification would have amounted to nothing more than the use of a known technique to improve similar devices in the same way, and combining prior art elements according to known methods to yield predictable results. Indeed, a POSITA would have recognized that applying Inokawa's teachings about two emitters having different wavelengths to Aizawa's sensor would have led to predictable results without significantly altering or hindering the functions performed by Aizawa's sensor. That is, a POSITA would have been motivated to provide the well-known feature of providing multiple emitters to a pulse sensor to achieve the predictable benefits that Inokawa's arrangement provides.

75. In addition to the rationale provided above, Inokawa provides an additional, or alternative, reason to add another emitter to Aizawa.

76. First, I note that Aizawa contemplates uploading data from its wrist sensor to an external base device but does not go into details about how such data transmission would be implemented. APPLE-1006, [0015], [0023], [0035]. Here, a POSITA would have been able to fill this gap by looking to Inokawa, which, as shown below, teaches a base device 17 (colored blue) that both charges and receives data from the pulse sensor 1 (colored red). APPLE-1008, [0060].

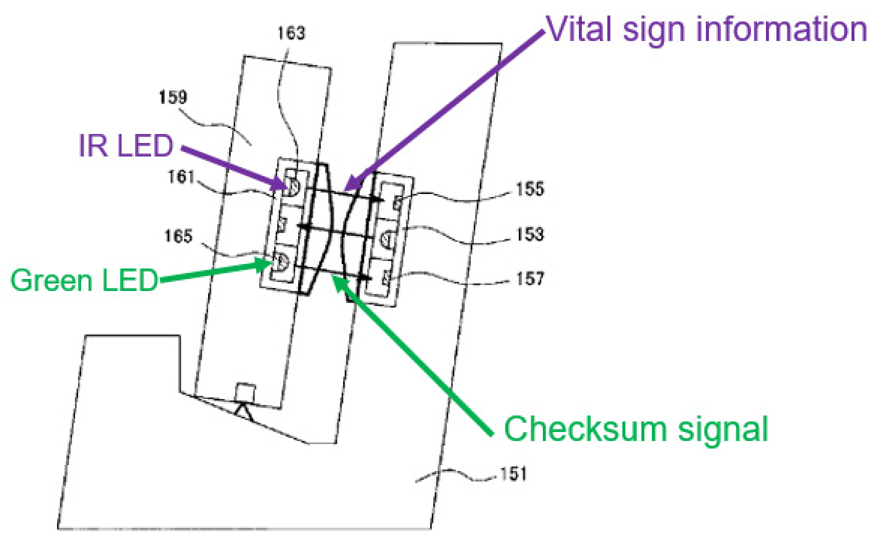


APPLE-1008, FIG. 3

77. Inokawa further teaches that, by using the sensor's infrared emitter to transmit data, "it is not necessary to use a wireless communication circuit or to establish connections via communication cable, which makes it possible to easily transmit vital sign information with few malfunctions and with a simple structure." APPLE-1008, [0007]. In view of such teaching, a POSITA would have been motivated and found it obvious and straightforward to incorporate Inokawa's base device and LED-based data transmission into Aizawa's sensor to, for instance, "make[] it possible to transmit vital sign information to the base device 17 accurately, easily, and without malfunction." *Id.,* [0077]. A POSITA would have also recognized that adding Inokawa's base device and LED-based data transmission scheme to Aizawa would allow Aizawa to upload data from its sensor

without having to use a separate cable and without having to incorporate a separate RF circuit into Aizawa's wrist sensor. APPLE-1008, [0007].

78. Here, I note that Inokawa's sensor is able to transmit data using only a single LED, for example operating at infrared wavelength. APPLE-1008, [0062]. However, as shown below, Inokawa also teaches that it's possible to use two different LEDs operating at different wavelengths to improve data transmission accuracy, namely by using a second LED operating at green wavelength, for instance, to transmit checksum information such that "the accuracy of data can be increased." *Id.*, [0111], [0044], [0048].



APPLE-1008, FIG. 19

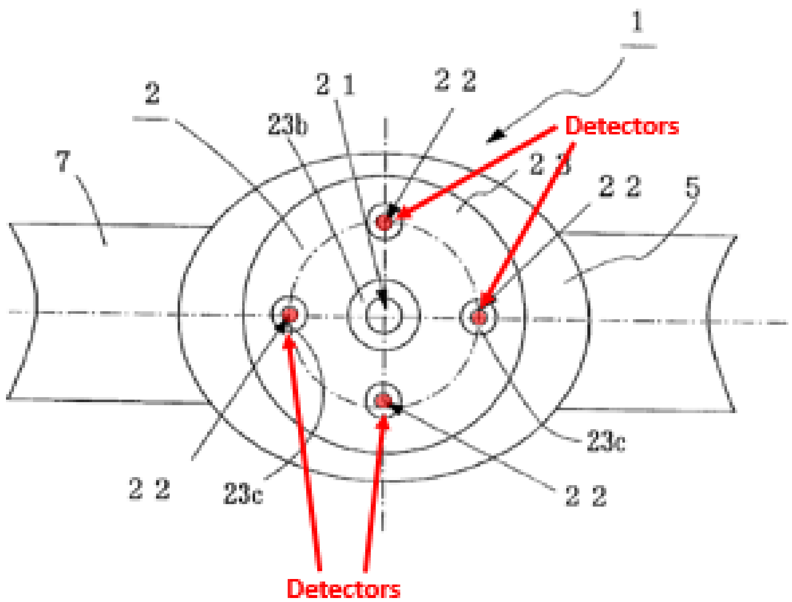
79. Accordingly, a POSITA would have found it obvious to supplement Aizawa's IR LED with an additional green LED, as per Inokawa, improve accuracy of data transmission from its sensor.

80. Indeed, a POSITA would have found it obvious to modify Aizawa with Inokawa in this manner because doing so entails the use of known solutions (*i.e.*, using a dual-LED system to more accurately transmit pulse data from a sensor to a base device) to improve similar systems and methods in the same way. For instance, a POSITA would have recognized that applying Inokawa's base device and dual-LED-based data transmission to Aizawa's sensor would have led to the predictable result of more accurate and convenient data transmission without significantly altering or hindering the functions performed by Aizawa's sensor. As such, a POSITA would have had a reasonable expectation of success in making this modification, and would have reasonably expected to reap benefits of simple and accurate data transmission. Indeed, it was common practice in the pulse oximeter field to centrally locate multiple emitters of different wavelengths, for example as further demonstrated by Mendelson-1988. APPLE-1015, 168; FIG. 2(A).

81. Thus, for reasons provided above, a POSITA would have found it obvious to split the single emitter of Aizawa into two emitters as in Inokawa in order to (i) acquire body motion information for improved pulse detection and/or (ii) more reliably transmit information from the sensor to a base device with less error. APPLE-1008, [0007], [0014], [0044], [0048], [0058], [0059], [0060], [0062], [0077], [0111].

[1b] a plurality of detectors configured to detect light that has been attenuated by tissue of the user, wherein the plurality of detectors comprise at least four detectors;

82. As illustrated below, Aizawa teaches "four photodetectors 22 disposed around the light emitting diode 21 symmetrically on a circle concentric to the light emitting diode 21." APPLE-1006, [0029], [0024], [0032].

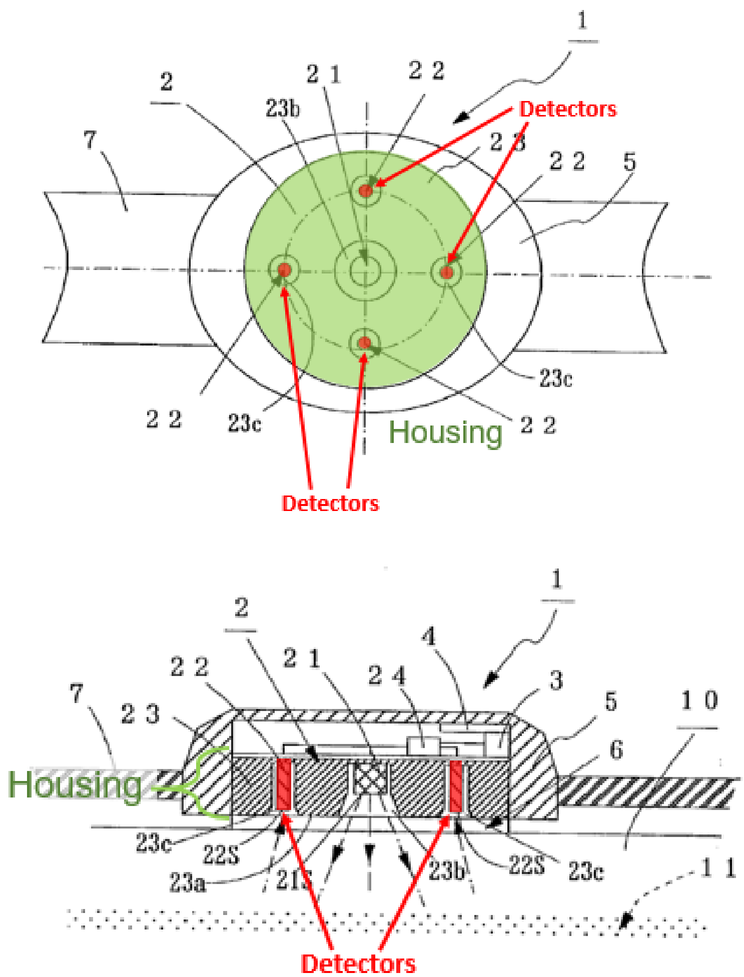


APPLE-1006, FIG. 1(a)

83. Moreover, Aizawa's photodetectors 22 are designed to detect light that is "reflected by a red corpuscle running through the artery 11 of the wrist 10 ... so as to detect a pulse wave." APPLE-1006, [0027]. Aizawa subsequently "detect[s] a pulse wave by amplifying the outputs of the photodetectors 22." *Id.*, [0023]. Thus, the detectors of Aizawa "detect light that has been attenuated by tissue of the user." *Id.*, [0027].

[1c] a housing configured to house at least the plurality of detectors in a circular portion of the housing; and

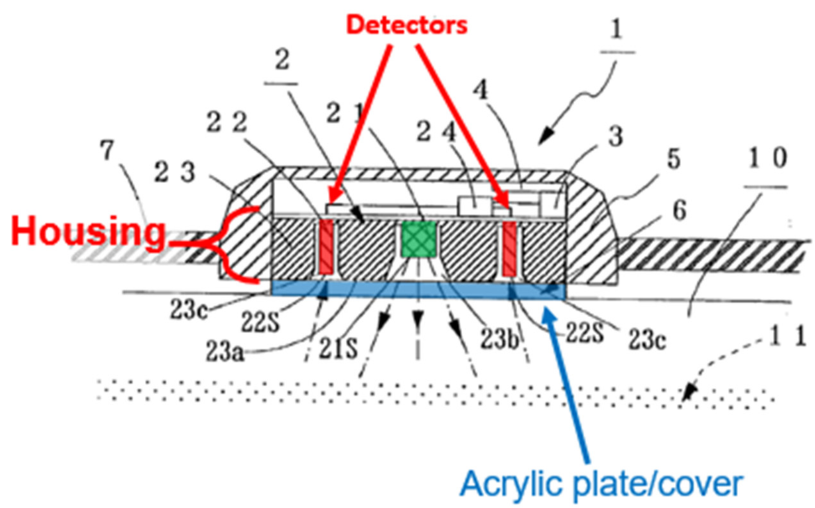
84. Aizawa teaches "a holder 23 for storing the above light emitting diode 21 and the photodetectors 22." APPLE-1006, [0023], [0024]. As further described below for [2], Aizawa also teaches a two-dimensional surface that supports the holder 23. *Id.* Thus, as shown below the holder and the flat surface are part of the housing element as required by this claim. As also shown below, the detectors are housed within a circular portion of the housing.



APPLE-1006, FIGS. 1(1)-(b)

[1d] a lens configured to be located between tissue of the user and the plurality of detectors when the noninvasive optical physiological sensor is worn by the user, wherein the lens comprises a single outwardly protruding convex surface configured to cause tissue of the user to conform to at least a portion of the single outwardly protruding convex surface when the noninvasive optical physiological sensor worn by the user and during operation of the noninvasive optical physiological sensor.

85. As explained above and shown below, Aizawa teaches a light permeable cover in the form of an acrylic transparent plate 6 (colored blue) that is mounted at the detection face 23a over at least a portion of the housing to cover the at least four detectors (colored red). APPLE-1006, [0023].

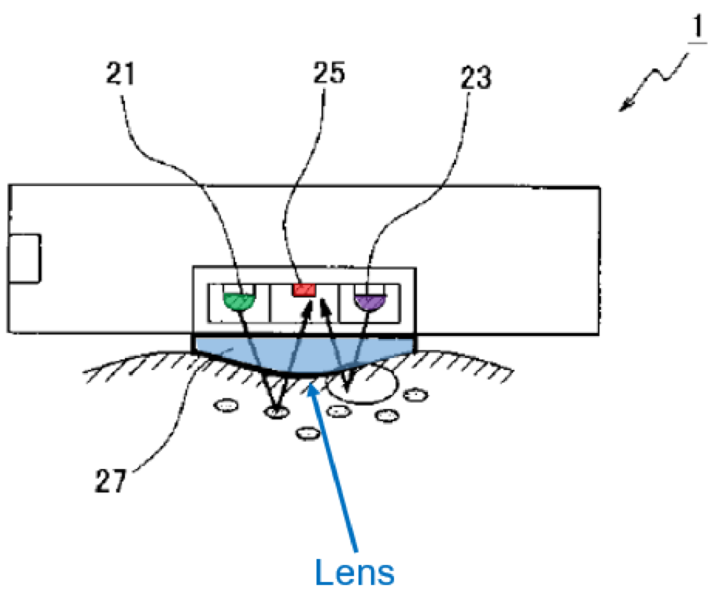


APPLE-1006, FIG. 1(b) (annotated), [0023]

86. However, the acrylic plate of Aizawa is flat and is not described as including a lens. But a POSITA would have been motivated and known how to modify the flat shape of Aizawa's acrylic plate to achieve a particular, desired objective. For example, Aizawa teaches that its light permeable cover (*i.e.*, acrylic transparent plate) helps improve "detection efficiency," but does not otherwise provide more

details about how, for instance based on its shape or material properties, such an effect may be achieved. APPLE-1006, [0030]. Indeed, a POSITA would have readily recognized that the shape of Aizawa's plate could be modified based on well-known techniques to help achieve Aizawa's objective of improving detection efficiency. APPLE-1006, [0013], [0030], [0032]; APPLE-1009 at 3:46-51.

87. As one example, a POSITA would have been able to look to Inokawa to enhance light collection efficiency, in particular by modifying the light permeable cover of Aizawa to include a convex protrusion that acts as a lens, as per Inokawa. APPLE-1008, FIG. 2. As illustrated below, Inokawa teaches a side lens 27 (colored blue) that is positioned between a pulse sensor and the user's skin. *Id.*

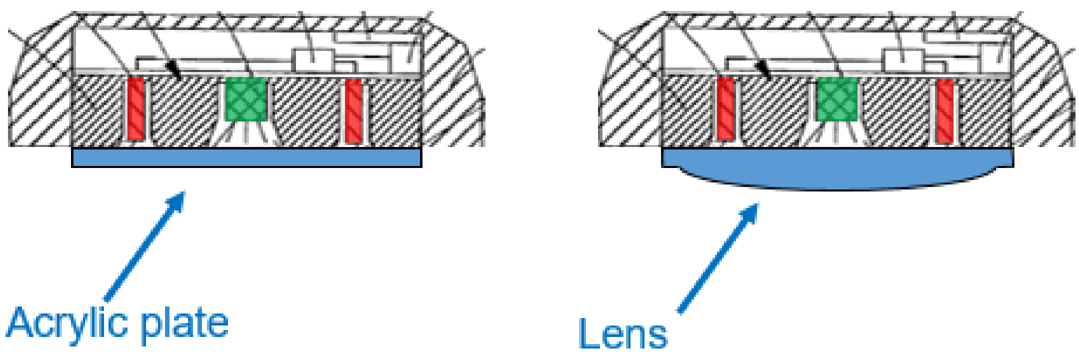


APPLE-1008, FIG. 2

88. Inokawa teaches that the "lens makes it possible to increase the light-gathering ability of the LED." *Id.*, [0015]. Thus, a POSITA would have sought to

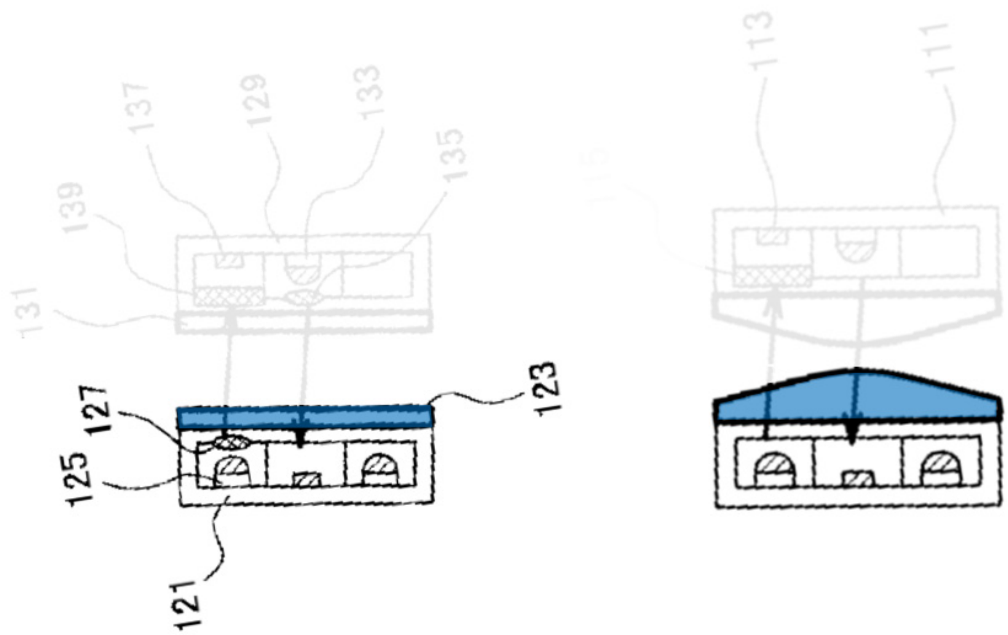
incorporate a convex lens as in Inokawa into Aizawa's acrylic plate to thereby increase light collection efficiency, in turn leading to more reliable pulse wave detection. The lens of Inokawa can provide this benefit by refracting and concentrating the light coming in through Aizawa's acrylic plate after being reflected by the blood and attenuated by the tissue of the user. Incidentally, because the path of light is reversible, the light collection function of Inokawa's lens would work the same way regardless of whether light is emitted toward the center (and detected by a centrally located photodiode) or emitted away from the center (and detected by a peripherally located photodiode).

89. In more detail, a POSITA would have found it obvious to combine the teachings of Aizawa and Inokawa such that the flat cover (left) of Aizawa is modified to include a lens (right) as per Inokawa in order to "increase the light-gathering ability." APPLE-1008, [0015]. Indeed, by positioning a lens above the optical components of Aizawa, as shown below, the modified cover will allow more light to be gathered and refracted toward the light receiving cavities of Aizawa, thereby further increasing the light-gathering ability of Aizawa beyond what is achieved through the tapered cavities. APPLE-1006, [0012], [0024].



APPLE-1006, FIG. 1(b)

90. A POSITA would have further understood *how* to incorporate the lens of Inokawa into Aizawa's cover, and further would have expected such a modification to succeed given the high degree of overlap between the two references. For example, as shown below, Inokawa teaches that its light permeable cover can be flat (left) so that "the surface is less prone to scratches," or alternatively be in the form of a lens (right) to "increase the light-gathering ability of the LED." APPLE-1008, [0015], [0016]. That is, depending on the desired objective of the user (*e.g.*, less scratches or improved light-gathering), the shape of the cover can be readily modified. Moreover, by choosing the material of the protrusion to be scratch-resistant, such as glass, it would have been obvious for a POSITA to achieve both benefits at once.

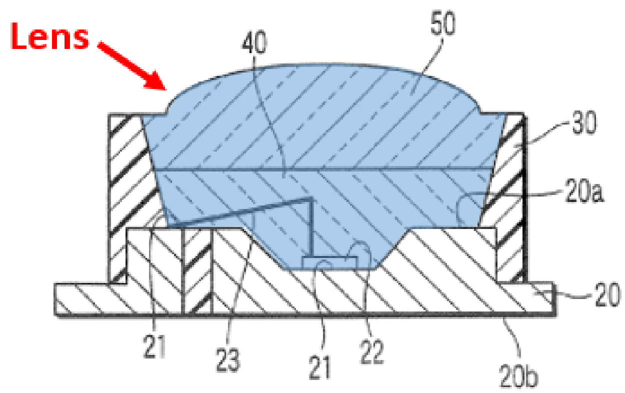


APPLE-1008, FIG. 17 (left), FIG. 16 (right)

91. A POSITA would have further recognized that the acrylic material used to make Aizawa's acrylic transparent plate 6 can be easily formed to include a lens. *See* APPLE-1009 at 3:46-51, FIG. 1; APPLE-1023, FIG. 6, [0022], [0032], [0035]. Indeed, many prior art references of this period, such as Nishikawa (shown below) demonstrate exactly how such a lens may be incorporated into a molded cover. APPLE-1023, FIG. 6, [0022], [0032], [0035]. In other words, a POSITA would have known that acrylic is a transparent material that can be readily transformed into various forms, including a lens, as needed due to its easy molding properties. *Id.* Thus, a POSITA preferring improved light collection efficiency over reduced susceptibility to scratches could have been able to easily modify Aizawa's cover to include a lens as per Inokawa. *Id.* Indeed, only a routine knowledge of sensor

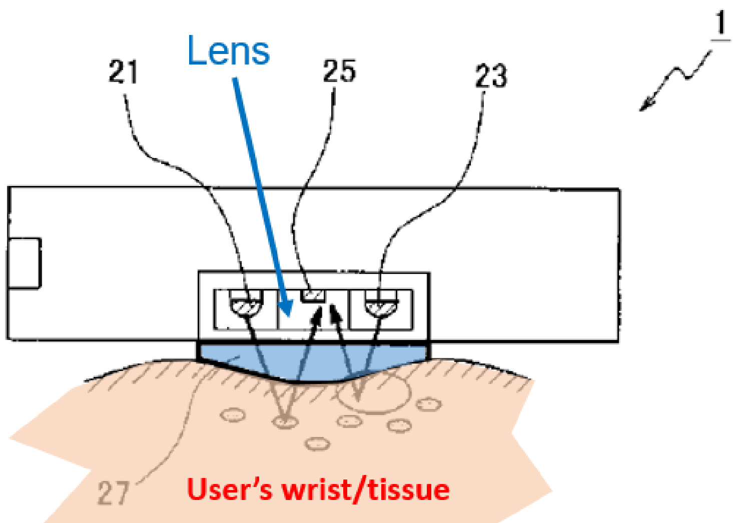
design and assembly, which were well within the skill of a POSITA, would be required to perform such modifications. Thus, to achieve the goal of improving light collection efficiency, which both Aizawa and Inokawa share, a POSITA would have been able to, with a reasonable expectation of success, modify Aizawa's light permeable cover to have a lens as taught by Inokawa.

FIG.6



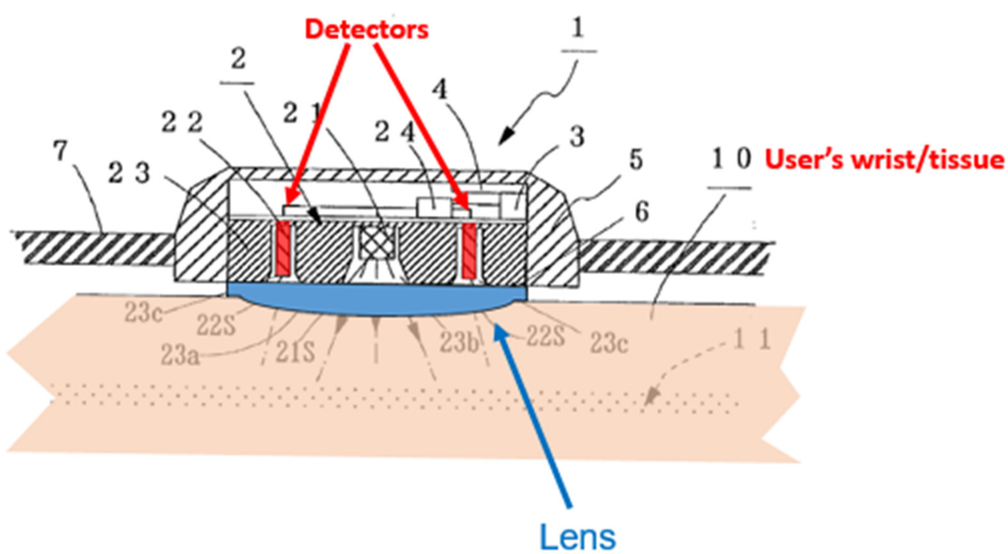
APPLE-1023, FIG. 6

92. Moreover, the light permeable cover of Aizawa is designed to be pressed toward the skin of the user with some pressure. APPLE-1006, [0006], [0026]. Being pressed into the skin in this manner will cause the tissue to conform to at least a portion of the protruding surface because the skin is less rigid than the light permeable cover, for example as demonstrated below by Inokawa where it can be seen that the user's tissue has deformed around the protruded surface of the cover.



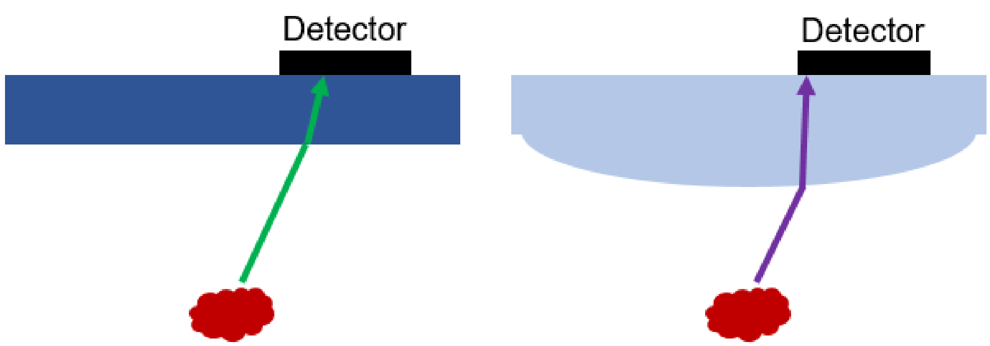
APPLE-1008, FIG. 2

93. Similarly, when the lens of Inokawa is incorporated into Aizawa as discussed above for element [1d], the protrusion will cause the tissue of the user, which is less rigid than the protrusion, to conform around the convex surface of the lens/protrusion when the device is pressed against the tissue during use.

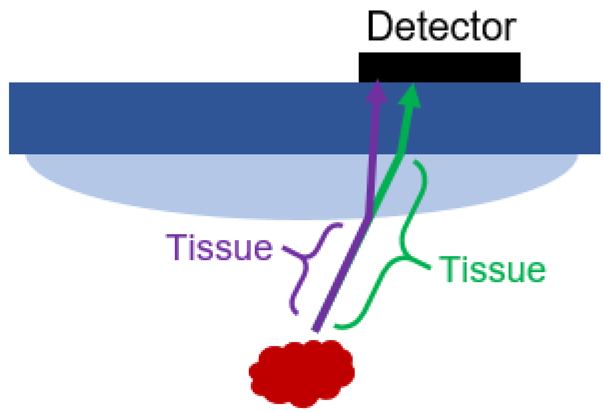


APPLE-1006, FIG. 1(b)

102. In more detail, I noted above for [1d] how the lens of Inokawa, which is used to modify Aizawa's cover, provides a condensing function by refracting the light passing through it. APPLE-1008, [0015], [0058]. As demonstrated through my drawings below, where the left figure shows the length of non-refracted light and the right figure shows the length of refracted light, such refraction of the incoming reflected light can shorten the path of the light before it reaches the detector. This is because the incoming light is "condensed" toward the center. APPLE-1008, [0015], [0058]. Thus, as demonstrated by the drawings below, both the total length of travel as well as the length through the tissue can be reduced.



103. Laying these two drawings on top of each other, as shown below, the shortened path length within the tissue for the purple (refracted) line can be clearly seen compared to the path length within the tissue of the green (non-refracted) line. The shortened *total* path length of the purple line compared to the green line can also be seen. Accordingly, the Aizawa-Inokawa combination, through its use of a condensing lens between the tissue and the detectors, serves to reduce a mean path length of light traveling to the at least four detectors.



104. [[INTENTIONALLY LEFT BLANK]]

G. Claim 8

[8] The noninvasive optical physiological sensor of claim 4, wherein the lens is configured to increase a signal strength per area of the plurality of detectors.

105. As explained above with respect to [1d], the Aizawa-Inokawa combination includes provides a convex lens that helps enhance the device's light-gathering ability. APPLE-1008, [0015], FIG. 2. Indeed, a POSITA would have known that a lens, as in Inokawa and as incorporated into Aizawa, would condense incoming light onto the detectors, thus increasing the signal strength per area of the detectors (since each detector area will receive more incoming light signals).

H. Claim 9

[9pre] An optical physiological measurement sensor comprising:

106. As I explained above in ¶ 68 for [1pre], the analysis for which I fully incorporate herein, the Aizawa-Inokawa combination discloses or renders obvious this element.

124. In the Aizawa-Inokawa combination I described above in ¶¶ 85-93 for [1d], the modified cover provides a window that allows light to pass through to the detectors. APPLE-1006, FIG. 1(b); APPLE-1008, [0015], [0058]. Indeed, the transparent cover in the Aizawa-Inokawa combination is held in place and surrounded by opaque structural elements of Aizawa, such that a portion of the lens is a window that allows light to pass through. A POSITA would have understood the housing of Aizawa, including its holder 23, to be opaque in order to be able to prevent unwanted ambient light from entering inside the housing. Moreover, because the lens acts as a light concentrator that improves the light-gathering ability of the modified device, the modified cover acts as a window that has a light concentrating function—*i.e.,* a light concentration window

IX. GROUND 1B – Claims 1-6, 8-16, 18, and 19 Are Rendered Obvious by Aizawa in view of Inokawa and Ohsaki

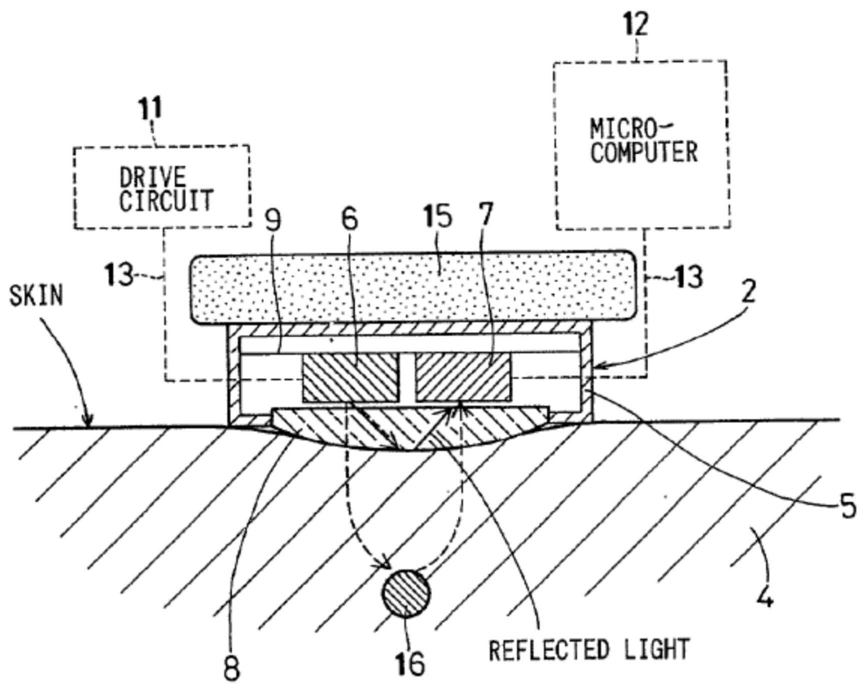
A. Claims 1-6, 8-16, 18, and 19

125. As I explained above in ¶¶ 85-93 with respect to element [1d], a POSITA would have been motivated to incorporate a lens-like protrusion of Inokawa into the cover of Aizawa to increase the light collection efficiency.

126. Ohsaki (APPLE-1014), which I briefly described above in ¶¶ 63-64, provides an alternative/additional rationale for why a POSITA would have modified the flat cover of Aizawa's acrylic plate into a protruded lens as per element [1d].

127. Among other things, Ohsaki teaches that adding a convex surface to its translucent board 8 (*i.e.*, light permeable cover) can help prevent the device from slipping on the tissue of the wearer compared to using a flat cover without such a protrusion. APPLE-1014, [0025].

FIG. 2



APPLE-1014, FIG. 2

128. Minimizing slippage between a user-worn sensor device and the tissue of the user was indeed a well-known objective in such devices. For example, Aizawa teaches using its acrylic transparent plate 6 (*i.e.*, light permeable cover) to improve "adhesion between the wrist 10 and the pulse rate detector 11." APPLE-1006, [0026], [0030]. While Aizawa doesn't discuss whether the shape of its acrylic plate could be modified to achieve this objective, a POSITA in possession of both

Aizawa and Ohsaki would have recognized that Ohsaki's addition of a convex protrusion to its light permeable cover could be similarly implemented in Aizawa's device to help achieve the two references' shared goal of minimizing slippage. *Id.* In other words, a POSITA seeking to achieve improved adhesion between the detector and the skin, as expressly recognized in Aizawa, would have been motivated and readily able to modify Aizawa's acrylic plate to have a convex shape as in Ohsaki. This would have allowed Aizawa's sensor device to remain better adhered to the skin and thereby increase its light-collecting efficiency. APPLE-1006, [0026], [0030]; APPLE-1014, [0025]. Additionally, a POSITA would have appreciated that the lens/protrusion in the Aizawa-Inokawa combination as detailed above in ¶¶ 89-98 would have provided a similar anti-slippage advantage due to the lens's convex shape, thereby providing an additional motivation for a POSITA to make the above-noted modification of Aizawa in view of Inokawa's lens.

129. The resulting Aizawa-Inokawa-Ohsaki combination satisfies all remaining elements of claims 1-6, 8-16, 18, and 19 in the same manner as previously described in Ground 1A, which is herein incorporated by reference.

X. GROUND 2 – Claims 1-6, 8-16, 18, and 19 Are Rendered Obvious by Mendelson-1988 in view of Inokawa

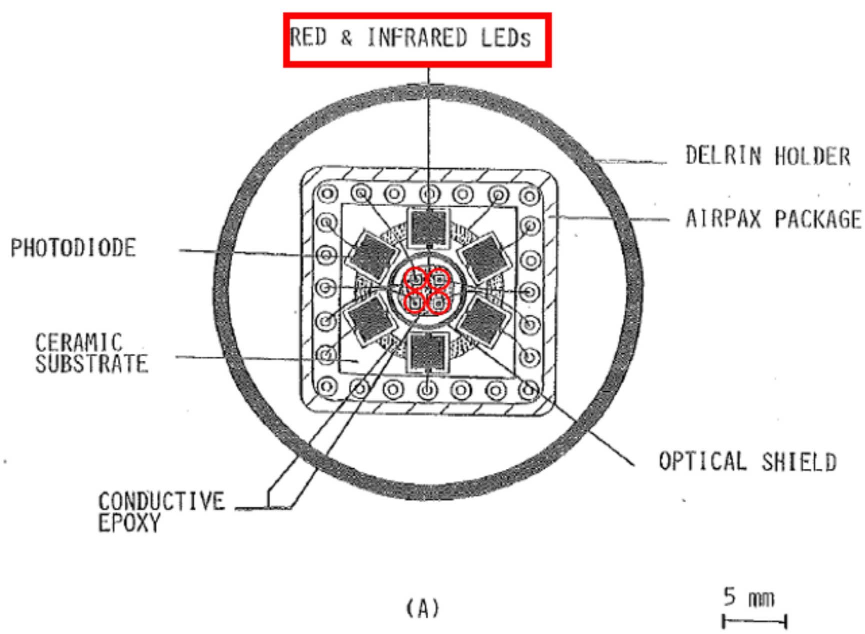
A. Claim 1

[1pre] A noninvasive optical physiological sensor comprising

130. Mendelson-1988 discloses "a new optical reflectance sensor suitable for noninvasive monitoring of arterial hemoglobin oxygen saturation with a pulse oximeter." APPLE-1015, Abstract, 167, 172. Hemoglobin oxygen saturation is one of the physiological parameters expressly mentioned in the '628 patent. APPLE-1001, Claim 16.

[1a] a plurality of emitters configured to emit light into tissue of a user;

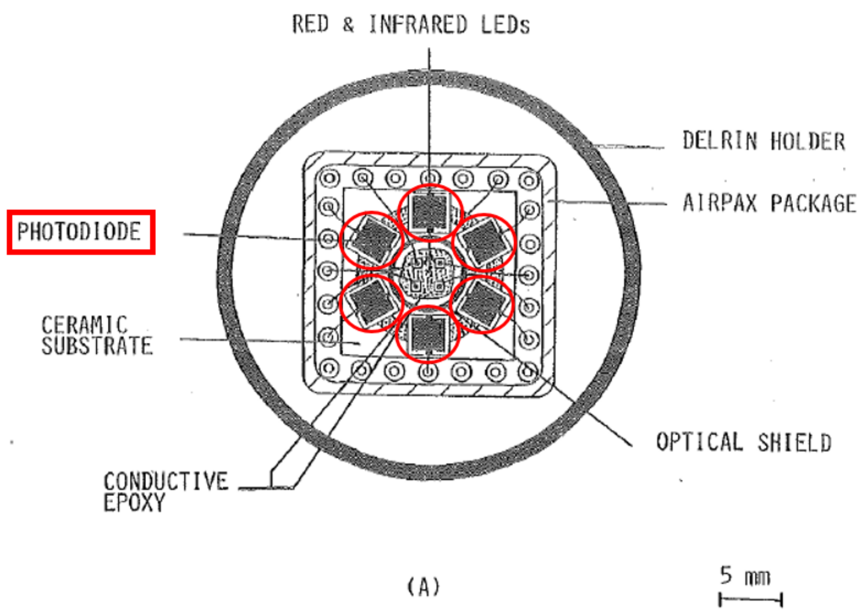
131. As illustrated below, Mendelson-1988 teaches using two red and two infrared LEDs that are centrally located within the device. APPLE-1015, 168. Red and infrared LEDs emit different wavelengths of light. *Id.* The light is emitted into the tissue of the user to be "diffused by the skin in all directions." *Id.*



APPLE-1025, FIG. 2(A)

[1b] a plurality of detectors configured to detect light that has been attenuated by tissue of the user, wherein the plurality of detectors comprise at least four detectors;

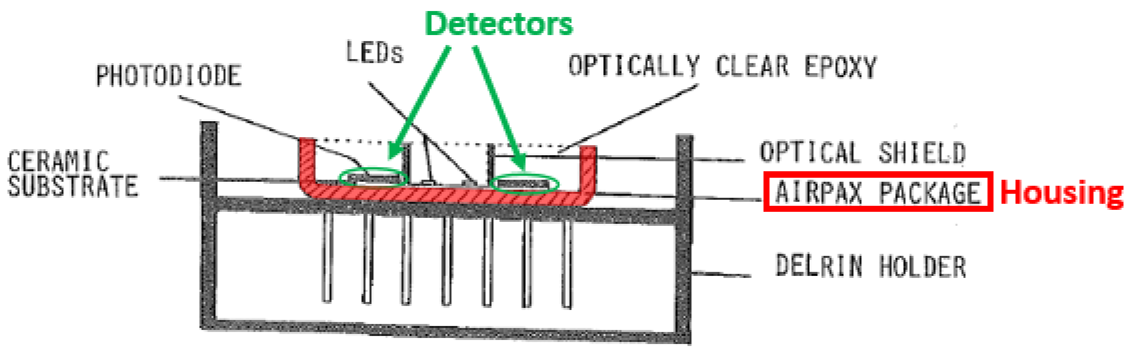
132. Mendelson-1988 teaches "six silicon photodiodes ... arranged symmetrically in a hexagonal configuration," as shown below, thus providing at least four detectors as claimed. APPLE-1015, 168. Output from the detectors are "current pulses ... which correspond to the red and infrared light intensities reflected from the skin" and are processed to respective photoplethysmographic waveforms. APPLE-1015, 169.



APPLE-1015, FIG. 2(A)

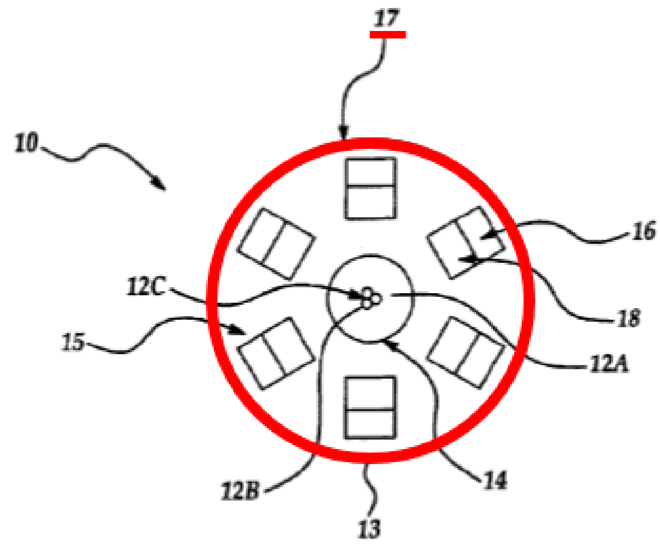
[1c] a housing configured to house at least the plurality of detectors in a circular portion of the housing; and

133. As I show below, Mendelson-1988 teaches that its emitters and detectors are mounted on a ceramic substrate and housed within an AIRPAX microelectronic package, which corresponds to the claimed housing. APPLE-1015, 168.



APPLE-1015, FIG. 2(B)

134. However, the particular housing shown in Mendelson-1988 appears to be rectangular. APPLE-1015, FIG. 2(A). Yet a POSITA would have recognized that microelectronic packaging as used in Mendelson-1988 comes in various shapes and size, for instance rectangular or circular. In fact, a patent authored by the same author of Mendelson-1988 (Dr. Mendelson) shows a similar detector configuration but one that is instead enclosed within a ***circular*** portion of the housing. APPLE-1025, 9:34-36, FIG. 7.



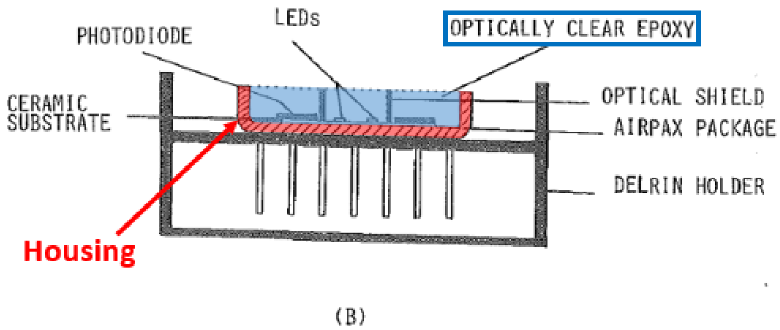
APPLE-1025, FIG. 7, 9:34-36

135. A POSITA would have found it obvious and actually quite routine to use a differently shaped housing, namely a circular one. *Id.* Indeed, using a circular housing having a circular wall, as evidenced by Mendelson-'799, was common practice well before the Critical Date, and there was nothing new or inventive about changing one housing shape for another

[1d] a lens configured to be located between tissue of the user and the plurality of detectors when the noninvasive optical physiological sensor is worn by the user, wherein the lens comprises a single outwardly protruding convex surface configured to cause tissue of the user to conform to at least a portion of the single outwardly protruding convex surface when the noninvasive optical physiological sensor is worn by the user and during operation of the noninvasive optical physiological sensor.

136. As shown below, Mendelson-1988 teaches encapsulating its emitters and detectors, which are within the housing (red), with an optically clear epoxy layer

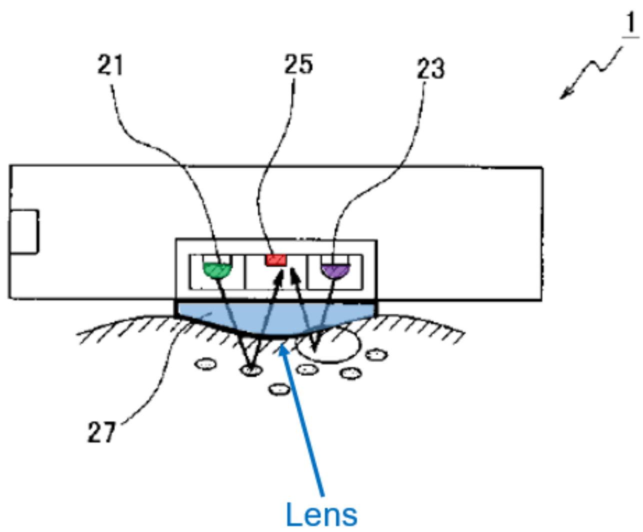
(blue). APPLE-1015, 168. This epoxy layer, therefore, provides a cover that is arranged above the housing and covers the detectors. *Id.*



APPLE-1015, FIG. 2(b)

137. However, beyond Mendelson-1988's disclosure that this cover is made from "optically clear epoxy," Mendelson-1988 does not provide further details. Among other things, the precise shape of this layer, for instance whether it's completely flat or slightly curved, is not mentioned. It's also not mentioned whether this epoxy layer protrudes slightly above the rest of the housing to, for instance, protect the user's skin from coming in direct contact with any sharp edges of the housing. Yet a POSITA would have recognized that the shape of the epoxy layer may be formed as needed to help further Mendelson'1988's goal of improving detection efficiency. APPLE-1015, 168, 173.

138. Indeed, as I described above, Inokawa teaches a similarly configured pulse sensor as in Mendelson-1988 but one in which a lens is positioned over the detectors to "increase the light-gathering ability of the LED as well as to protect the LED or [detector]." APPLE-1008, [0015], [0058].

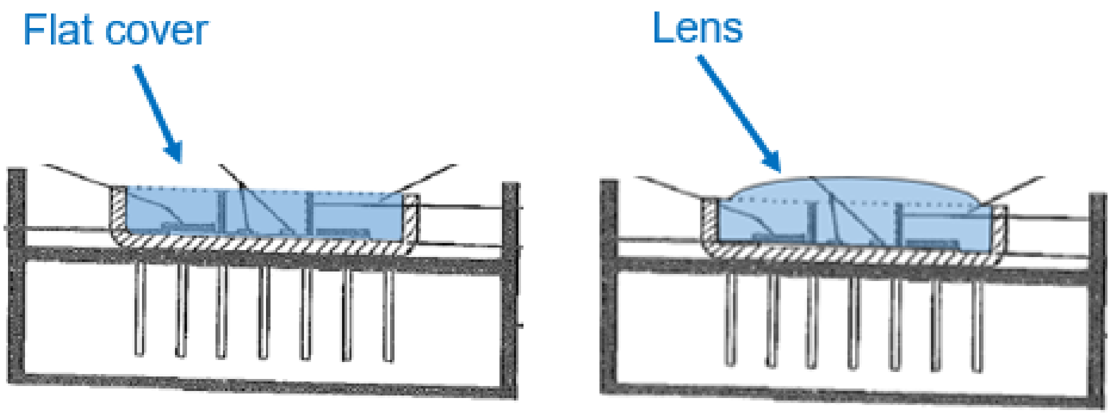


APPLE-1008, FIG. 2

139. Accordingly, a POSITA would have been motivated to incorporate the lens of Inokawa into to cover of Mendelson-1988 in order to increase the light collection efficiency. A POSITA would have been particularly interested in making such a modification because Mendelson-1988 shares a similar goal of maximizing "reflectance photoplethysmographic signals." APPLE-1015, 173. The lens of Inokawa provides precisely this benefit to Mendelson'1988's device by providing a protective cover that further refracts and concentrates the incoming light beams to thereby enhance the light collection efficiency. APPLE-1008, [0015], [0058].

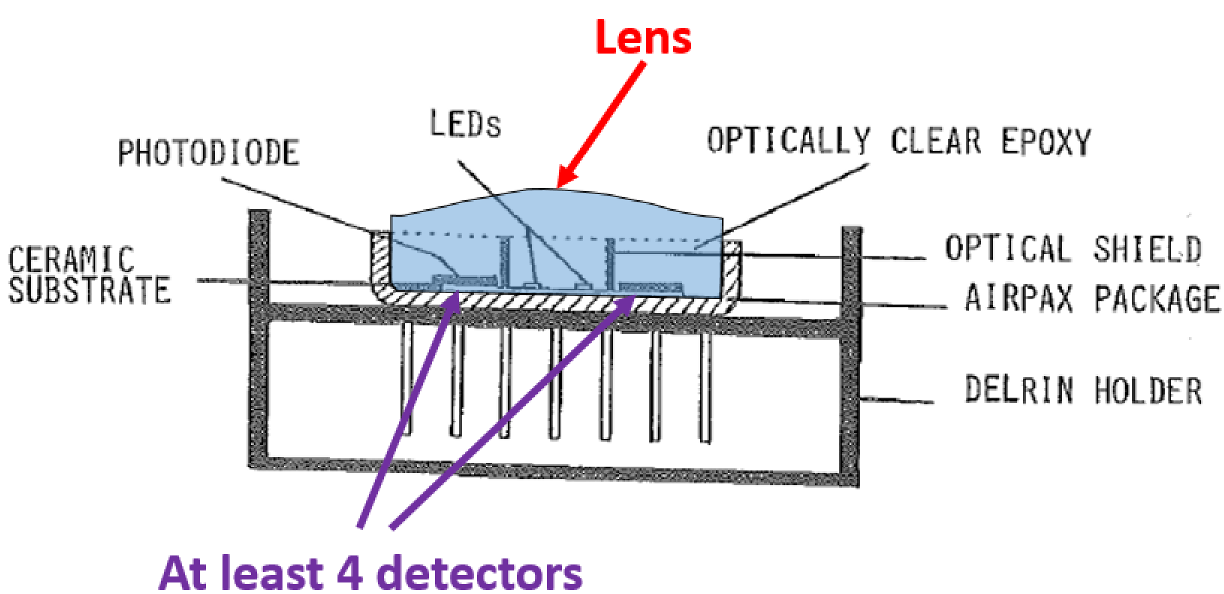
140. Indeed, as illustrated below, the device resulting from this combination of Mendelson-1988 and Inokawa would have modified the flat epoxy cover (left) with

a curved one as per Inokawa (right) to thereby "increase the light-gathering ability." APPLE-1008, [0015].



APPLE-1015, FIG. 2(B)

141. In this way, reflected light headed toward the detectors is refracted and condensed as it passes the lens/protrusion. APPLE-1008, [0015], [0058].

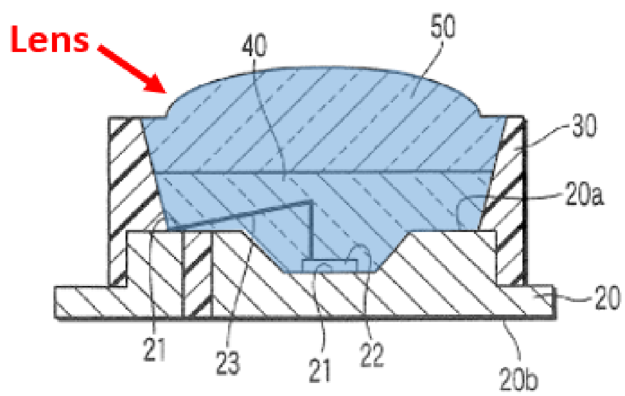


APPLE-1015, FIG. 2(B)

142. A POSITA would have understood how to implement Inokawa's lens in Mendelson-1988 with a reasonable expectation of success based, among other things, on the significant overlap between these two references. Indeed, the above-described modification would require only routine knowledge of sensor design and assembly, which were well within the skill of a POSITA prior to the Critical Date.

143. Moreover, a POSITA would have easily understood how to modify the epoxy layer of Mendelson-1988 to achieve the desired shape. Indeed, Nishikawa, shown below, teaches that a clear epoxy layer as in Mendelson-1988 can be molded into a lens. APPLE-1023, [0022], [0032], [0035].

FIG. 6

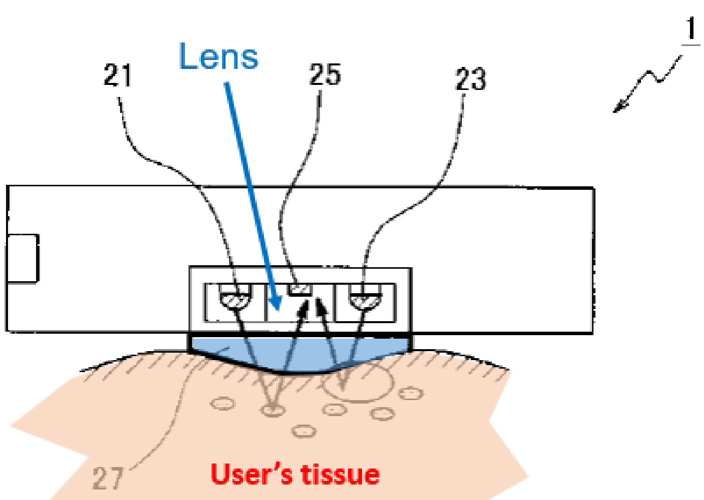


APPLE-1023, FIG. 6

144. Notably, both the optical encapsulation layer of Mendelson-1988 and the lens layer of Nishikawa are made from the same material, optically clear epoxy, and thus the interface between the encapsulation portion and the lens portion will not adversely affect the optical performance of the modified system. APPLE-1023, [0037]. Thus, to help achieve Mendelson-1988's and Inokawa's shared goal

of improving light collection efficiency, a POSITA would have been motivated and able to modify Mendelson-1988's epoxy cover to include a lens as per Inokawa with a reasonable expectation of success.

145. Moreover, the epoxy cover of Mendelson-1988 is designed to be attached directly to the user's skin. APPLE-1015, 169. Being pressed into the skin in this manner will cause the tissue of the user to conform to at least a portion of the outwardly protruding convex surface because the skin is more pliable than the light permeable cover, for example as demonstrated below by Inokawa where it can be seen that the user's tissue has deformed around the convex surface of the cover. APPLE 1008, [0099], [0107], FIGS. 2, 3, 16, 19.



APPLE-1008, FIG. 2

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent of:	Poeze et al.	
U.S. Patent No.:	10,376,191	Attorney Docket No.: 50095-0011IP1
Issue Date:	Aug. 13, 2019	
Appl. Serial No.:	16/409,515	
Filing Date:	May 10, 2019	
Title:	MULTI-STREAM DATA COLLECTION SYSTEM FOR NONINVASIVE MEASUREMENT OF BLOOD CONSTITUENTS	

SECOND DECLARATION OF DR. THOMAS W. KENNY

I hereby declare that all statements made of my own knowledge are true and that all statements made on information and belief are believed to be true. I further declare that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of the Title 18 of the United States Code.

Dated: December 6, 2021 By: ______________________

Thomas W. Kenny, Ph.D.

4. I have no financial interest in the party or in the outcome of this proceeding. I am being compensated for my work as an expert on an hourly basis. My compensation is not dependent on the outcome of these proceedings or the content of my opinions.

5. In writing this declaration, I have considered the following: my own knowledge and experience, including my work experience in the fields of mechanical engineering, computer science, biomedical engineering, and electrical engineer; my experience in teaching those subjects; and my experience in working with others involved in those fields. In addition, I have analyzed various publications and materials, in addition to other materials I cite in my declaration.

6. My opinions, as explained below, are based on my education, experience, and expertise in the fields relating to the '191 Patent. Unless otherwise stated, my testimony below refers to the knowledge of one of ordinary skill in the fields as of the Critical Date, or before.

II. Ground 1 Establishes Obviousness

A. Inokawa's lens enhances the light-gathering ability of Aizawa

7. As I previously explained in the Original Declaration, Inokawa ***very generally*** describes a "lens [that] makes it possible to increase the light-gathering ability" of a reflectance type pulse sensor, APPLE-1008, [0015], [0058], FIG. 2, and, based on this disclosure, a POSITA would have been motivated to incorporate "an Inokawa-like lens into the cover of Aizawa to increase the light collection efficiency...." APPLE-1003, ¶¶86-89. In a significant extrapolation from the very simple and

purely illustrative description in Inokawa, Patent Owner provides two incorrect arguments. First, Patent Owner claims that Inokawa's disclosure is narrowly-limited to a particular lens that somehow is only capable of operation with peripheral emitters and a central detector. Second, the Patent Owner claims that the lens of Inokawa directs all incoming light rays "to the center of the sensor" and would "direct light ***away*** from the ***periphery***-located detectors as in Aizawa," regardless of the direction of light propagation of each ray, which is a violation of elementary laws of light propagation that would be familiar to a POSITA. POR, 15, 19; *see also* APPLE-1034, 40:4-11 ("...as I describe in my Declaration...if you have a convex surface...***all light reflected*** or otherwise would be condensed or directed towards the center."). Based on these two incorrect claims, the Patent Owner insists that there would be no motivation to combine.

8. Patent Owner's misinformed understanding of Inokawa's lens as well as lenses in general is demonstrated by their description of Inokawa's lens 27 as "focus[ing] light from LEDs (21, 23)...***to a single detector (25) in the center***" and "direct[ing] incoming light ***to the centrally located detector***." POR, 14; *see also* APPLE-1034, 40:4-11 ("...as I describe in my Declaration...if you have a convex surface...***all light*** reflected or otherwise would be condensed or directed towards the center.").

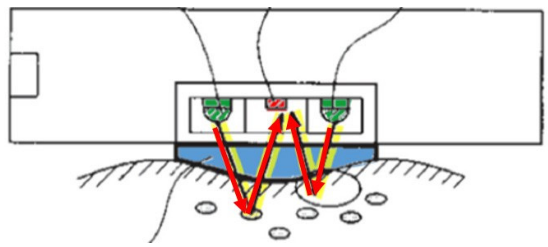
9. A correct understanding of Inokawa's lens as well as of reflectance type pulse sensors in general (like those disclosed by each of Aizawa, Inokawa, and Mendelson-1988) readily exposes Patent Owner's flawed rationale. Indeed, as I noted during

deposition, a POSITA would understand that Inokawa's lens generally improves "light concentration at pretty much all of the locations under the curvature of the lens," as opposed to only at a single point at the center as asserted by Patent Owner. Ex. 2006, 164:8-16. Indeed, as further explained below, a POSITA would have understood the following to be true—that a cover featuring a convex protrusion would improve Aizawa's signal-to-noise ratio by causing more light backscattered from tissue to strike Aizawa's photodetectors than would have with a flat cover. APPLE-1051, 52, 86, 90; APPLE-1052, 84, 87-92, 135-141; APPLE-1046, 803-805; APPLE-1006, FIGS. 1(a)-1(b). The convex cover enhances the light-gathering ability of Aizawa's sensor.

i. Masimo ignores the well-known principle of reversibility

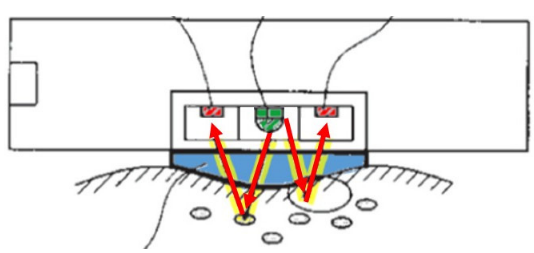
10. The well-known optical ***principle of reversibility*** readily dispels Masimo's claim that "a convex cover condenses light towards the center of the sensor and away from the periphery," when applied to Aizawa. POR, 15; APPLE-1052, 87-92; APPLE-1049, 106-111. Specifically, according to the principle of reversibility, "a ray going from P to S will trace the same route as one from S to P." APPLE-1052, 92, 84; APPLE-1049, 101, 110; APPLE-1036, 80:20-82:20. Importantly, the principle dictates that rays that are not completely absorbed by user tissue will propagate in a reversible manner. In other words, every ray that completes a path through tissue from an LED to a detector would trace an identical path through that tissue in reverse, if the positions of the LED emitting the ray and the receiving detector were swapped.

APPLE-1052, 92. To help explain, I have annotated Inokawa's FIG. 2 (presented below) to illustrate the principle of reversibility applied in the context of a reflective optical physiological monitor. As shown, Inokawa's FIG. 2, illustrates two example ray paths from surrounding LEDs (green) to a central detector (red):



APPLE-1008, FIG. 2 (annotated)

11. As a consequence of the principle of reversibility, a POSITA would have understood that if the LED/detector configuration were swapped, as in Aizawa, the two example rays would travel identical paths in reverse, from a central LED (red) to surrounding detectors (green). A POSITA would have understood that, for these rays, any condensing/directing/focusing benefit achieved by Inokawa's cover (blue) under the original configuration would be identically achieved under the reversed configuration:



APPLE-1008, FIG. 2 (annotated)

12. When factoring in additional scattering that may occur when light is reflected within human tissue, reversibility holds for each of the rays that are not completely absorbed; consequently, "if we're concerned with the impact of the lens on the system,

it's absolutely reversible." EX. 2006, 209:19-21, 207:9-209:21 ("one could look at any particular randomly scattered path…and the reversibility principle applies to all of the pieces [of that path] and, therefore, applies to the aggregate").

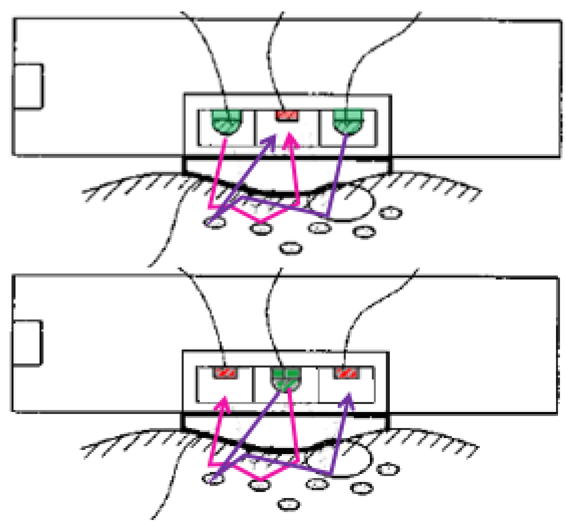
13. An example of reversibility in a situation with diffuse light, such as is present when LEDs illuminate tissue, is shown below from Hecht's Figure 4.12.

Figure 4.12 (a) Specular reflection. (b) Diffuse reflection. (Photos courtesy Donald Dunitz.)

14. In this figure 4.12a, collimated light is incident on a smooth surface, and exhibits specular reflection, in which parallel light rays encounter and are reflected from the surface and remain parallel. A POSITA would certainly understand specular reflection. In the case of the reflection as shown in Figure 4.12b, the random roughness of the surface scatters the incoming rays into many directions, and the resulting light would appear to be diffuse. However, even in this circumstance, the principle of reversibility applies–each individual ray can be reversed such that a ray travelling to the surface and scattered in a random direction can be followed backwards along exactly the same path.

15. In more detail, and as shown with respect to the example paths illustrated below (which include scattering within tissue), each of the countless photons

travelling through the system must abide by Fermat's principle. APPLE-1049, 106-111. Consequently, even when accounting for various random redirections and partial absorptions, each photon traveling between a detector and an LED would take the quickest (and identical) path along the segments between each scattering event, even if the positions of the detector and LED were swapped.



16. To better understand the effect of a convex lens on the propagation of light rays towards or away from the different LEDs or detectors, the first and last segment of the light path may be representative of the light propagation of the various light rays. In the figures above, starting at the upper left, there is a pink-colored light ray emerging from the green LED and passing through the convex lens and entering the tissue. On the lower left, there is a pink-colored light ray leaving the tissue and entering the convex lens. As drawn, these rays are the same in position and orientation, except that the direction is exactly reversed. This illustration is consistent with the Principle of Reversibility as applied to this pair of possible light rays. According to the principle of reversibility, the upper light path from the LED to the

first interaction with a corpuscle is exactly reversed. This same behavioral pattern applies to all of the segments of the many light paths that cross the interface at the surface of the convex lens. Importantly, in this example, the convex lens does not refract the incoming ray in a different direction from the outgoing ray, e.g., in a direction towards the center different from the outgoing ray. As required by the principle of reversibility, this incoming ray follows the same path as the outgoing ray, except in the reverse direction. This statement is true for every segment of these light paths that crosses the interface between the tissue and the convex lens. Any ray of light that successfully traverses a path from the LED to the detector, that path already accounts for the random scattering as that scattering is what allowed the ray to go from the LED to a detector along the path to thereby be subsequently detected by the detector. A POSITA would have understood that the path is an aggregation of multiple segments and that the path is reversible as each of its segments would be reversible, consistent with Fermat's principle.

17. The statement about the reversibility of the segments of the light path which cross the interface between tissue and convex lens is consistent with the well-known and well-established Snell's law, which provides a simple algebraic relation between the angles of incidence and refraction as determined by the two indices of refraction. And Snell's law supports the basic understanding that the path of the light rays to/from a scattering event across the interface to/from the convex lens and on to/from the LED or photodetector must be reversible.

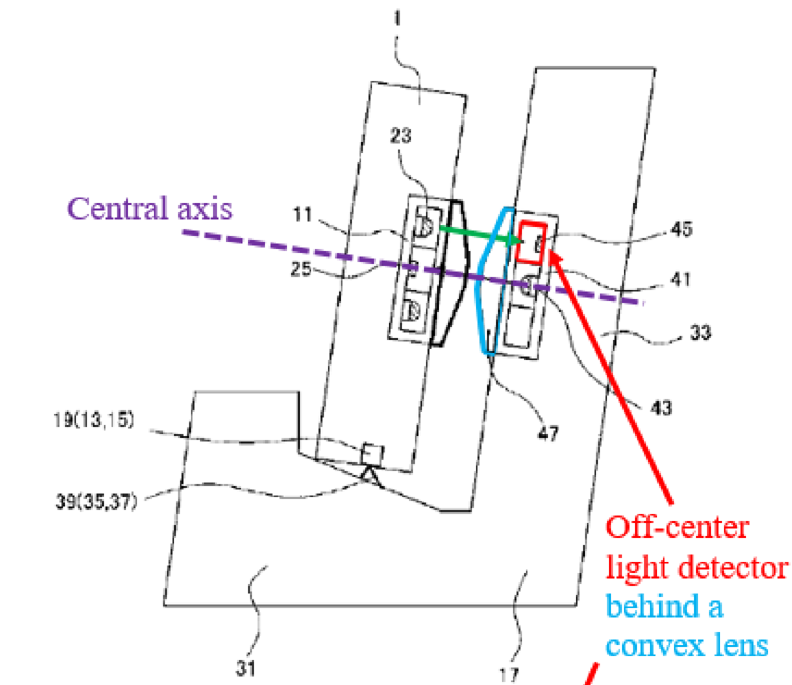
18. Based on this understanding of light rays and Snell's law, a POSITA would have understood that the positions of the emitters and detectors can be swapped in the proposed combination, and that the light paths from the initial situation would be reversed in the altered situation.

19. When confronted with this basic principle of reversibility during deposition, Dr. Madisetti refused to acknowledge it, even going so far as to express ignorance of "Fermat's principle, ***whatever that is***." APPLE-1034, 89:12-19. Yet Fermat's principle, which states that a path taken by a light ray between two points is one that can be traveled in the least time, regardless of the direction of travel, is one of the most fundamental concepts in optics/physics and plainly requires the basic principle of reversibility. APPLE-1052, 87-92; APPLE-1049, 106-111. This is in no way a new theory, as this core concept dates back many years, and is offered in Aizawa itself. Indeed, ***Aizawa recognizes this reversibility***, stating that while the configurations depicted include a central emitter surrounded by detectors, the "same effect can be obtained when…a plurality of light emitting diodes 21 are disposed around the photodetector 22." APPLE-1006, [0033]; EX. 2006, 209:19-21.

20. Masimo's technically and factually flawed argument is exposed by multiple prior art references, including the Ohsaki and Inokawa references which are the key elements of our combinations. As shown in the figures below, Ohsaki and Inokawa both show embodiments which use a convex lens to direct light to detectors that are not located at the center of a sensor. APPLE-1014, FIG. 2; APPLE-1008, FIG. 3.

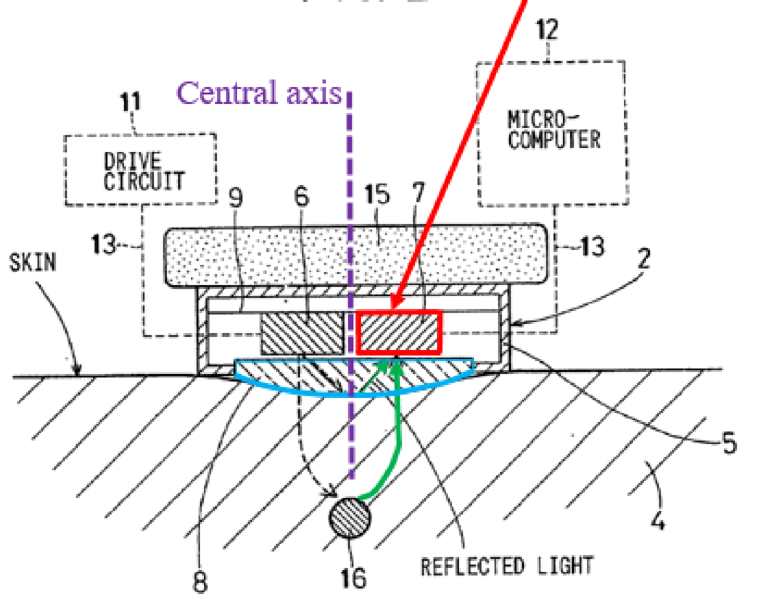
In Inokawa's Figure 2, an off-center emitter and sensor are configured to send and receive text messages, and are capable of success, even though the detector is not positioned at the center.

(FIG. 3)



APPLE-1008, FIG. 3

FIG. 2



APPLE-1014, FIG. 2

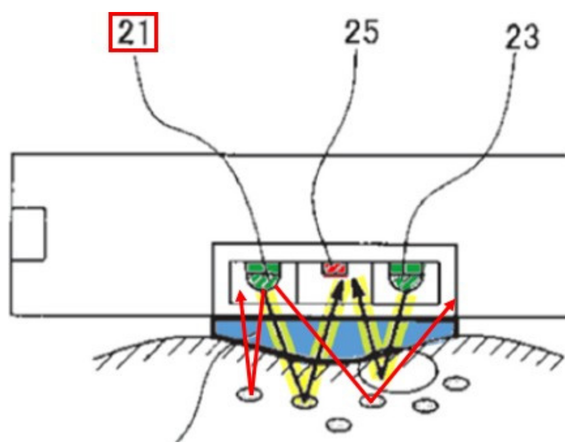
21. If, as asserted by the Patent Owner, a convex lens is required to condense, direct, or focus the light to the center, the embodiments disclosed by Ohsaki and Inokawa would all fail because there is no detector at the center to detect all of the light that would be directed towards the center by the convex board. The Ohsaki and Inokawa embodiments (reproduced above) do not show or otherwise teach that its convex board directs all light towards the center.

22. In short, based at least on the principle of reversibility, a POSITA would have understood that both configurations of LEDs and detectors—*i.e.*, with the LED at the center as in Aizawa or with the detector at the center as in Inokawa—would identically benefit from the enhanced light-gathering ability of a convex lens/protrusion.

ii. Masimo ignores the behavior of scattered light in a reflectance-type pulse sensor

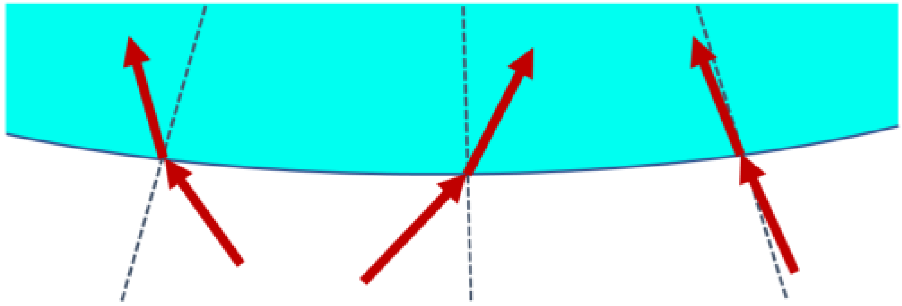
23. Because Aizawa is a reflectance-type pulse sensor that receives diffuse, backscattered light from the measurement site, its cover/lens cannot focus all incoming light toward the sensor's center. Ex. 2006, 163:12-164:2 ("A lens in general…doesn't produce a single focal point"). Indeed, reflectance-type sensors work by detecting light that has been "partially reflected, transmitted, absorbed, and scattered by the skin and other tissues and the blood before it reaches the detector." APPLE-1051, 86. A POSITA would have understood that light which backscatters from the measurement site after diffusing through tissue reaches the active detection area from various random directions and angles. APPLE-1046, 803; APPLE-1051, 90, 52.

24. As noted above, basic law of refraction, namely Snell's law, dictates this behavior of light. APPLE-1052, 84; APPLE-1049, 101; APPLE-1036, 80:20-82:20; APPLE-1051, 52, 86, 90. For example, referring to Masimo's version of Inokawa's FIG. 2, further annotated below to show additional rays of light emitted from LED 21, it is clearly seen how some of the reflected/scattered light from the measurement site does not reach Inokawa's centrally located detector:



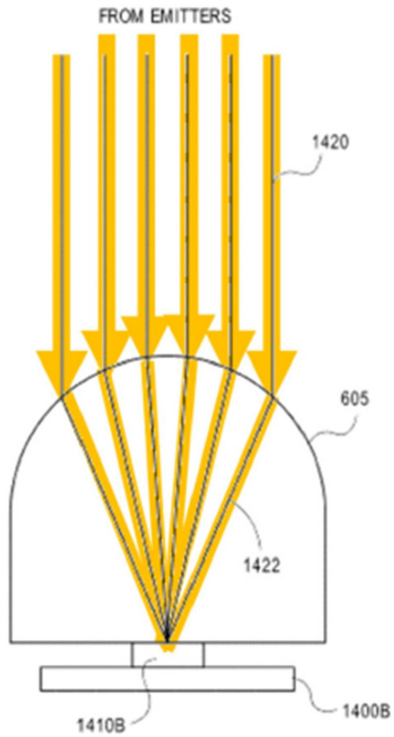
APPLE-1008, FIG. 2 (annotated); POR, 13.

25. For these and countless other rays that are not shown, there is simply no way for a cover to focus all light at the center of the sensor device. APPLE-1052, 84; APPLE-1049, 101; APPLE-1036, 80:20-82:20. The illustration I provide below shows how Snell's law determines a direction of a backscattered ray within a convex cover, thus providing a stark contrast to Masimo's assertions that all such rays must be redirected to or towards the center:



26. Indeed, far from focusing light to the center as Masimo contends, Ohsaki's convex cover provides a slight refracting effect, such that light rays that may have otherwise missed the detection area are instead directed toward that area as they pass through the interface provided by the cover. This is particularly true in configurations like Aizawa's in which light detectors are arranged symmetrically about a central light source, so as to enable backscattered light to be detected within a circular active detection area surrounding that source. APPLE-1051, 86, 90. The slight refracting effect is a consequence of the similar indices of refraction between human tissue and a typical cover material (e.g., acrylic). APPLE-1044, 1486; APPLE-1045, 1484).

27. To support the misguided notion that a convex cover focuses all incoming light at the center, Masimo relies heavily on the '191 Patent's FIG. 14B (reproduced below):



APPLE-1001, FIG. 14B (as annotated at POR, 18, 25)

28. Masimo and Dr. Madisetti treat this figure as an illustration of the behavior of all convex surfaces with respect to all types of light, and conclude that "a convex surface condenses light away from the periphery and towards the sensor's center." POR, 14; APPLE-1034 ("…a POSA viewing [FIG. 14B]…would understand that light, ***all light***, light from the measurement site is being focused towards the center").

29. But the incoming collimated light shown in FIG. 14B is not an accurate representation of light that has been reflected from a tissue measurement site. The light rays (1420) shown in FIG. 14B are collimated (i.e., travelling paths parallel to one another), and each light ray's path is perpendicular to the detecting surface.

30. While each of Inokawa, Aizawa, and Mendelson-1988 are directed to a reflectance-type pulse sensor that detects light that has been backscattered from the

measurement site, the scenario depicted in FIG. 14B shows a transmittance-type configuration where collimated or nearly-collimated light is "attenuated by body tissue," not backscattered by it. APPLE-1001, 36:11-13. Indeed, FIG. 14I of the '191 Patent puts FIG. 14B in proper context, showing how light from the emitters is transmitted through the entire finger/tissue before being received by the detectors on the other side:

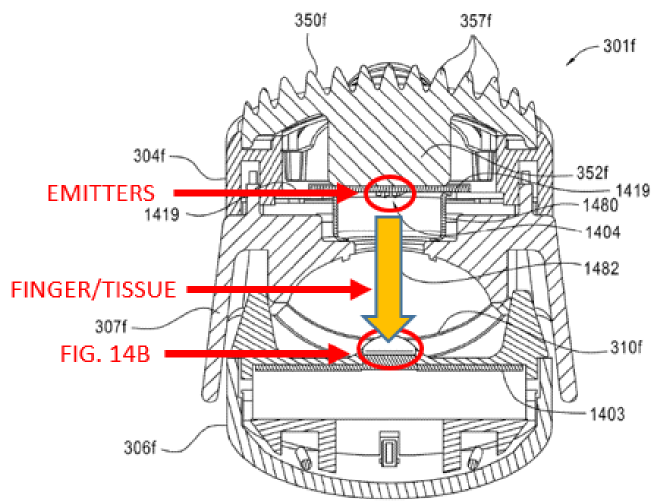
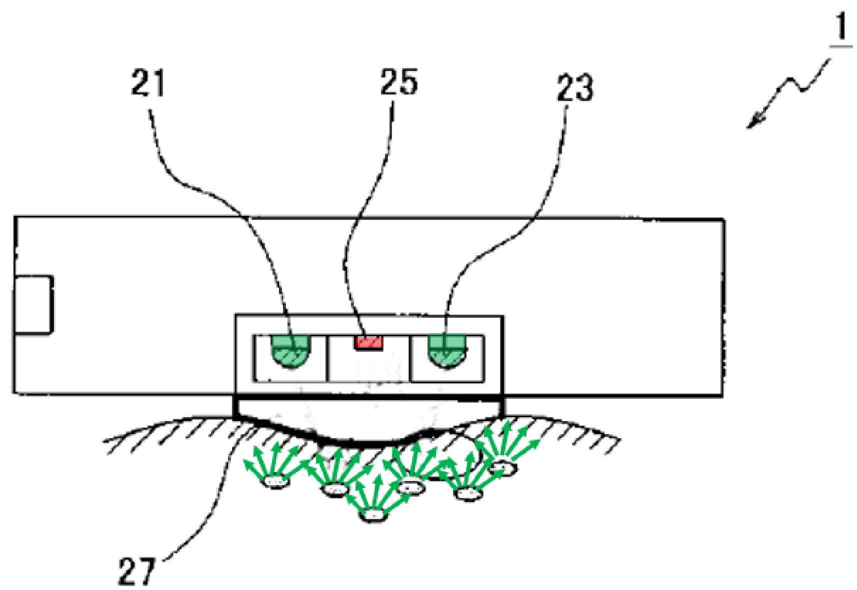


FIG. 14I

31. By contrast, the detector(s) of reflectance type pulse detectors detect light that has been "partially reflected, transmitted, absorbed, and scattered by the skin and other tissues and the blood before it reaches the detector." APPLE-1051, 86. For example, a POSITA would have understood from Aizawa's FIG. 1(a) that light that backscatters from the measurement site after diffusing through tissue reaches the circular active detection area provided by Aizawa's detectors from various random directions and angles, as opposed to all light entering from the same direction and at

the same angle as shown above in FIG. 14B. APPLE-1051, 52, 86, 90; APPLE-1046, 803-805; *see also* APPLE-1012, FIG. 7. Even for the collimated light shown in FIG. 14B, the focusing of light at the center only occurs if the light beam also happens to be perfectly aligned with the axis of symmetry of the lens. If for example, collimated light were to enter the FIG. 14B lens at any other angle, the light would focus at a different location in the focal plane. Further, if the light were not collimated, so that rays enter the lens with a very wide range of incident angles, there would be no focus at all, and many rays will be deflected away from the center. Moreover, since “the center” takes up a very small portion of the total area under the lens, the majority of rays associated with diffuse light entering the lens would arrive at locations away from the center.

32. The light rays from a diffuse light source, such as the LED-illuminated tissue near a pulse wave sensor or a pulse oximeter, include a very wide range of angles and directions, and cannot be focused to a single point/area with optical elements such as lenses and more general convex surfaces. The example figure below illustrates light rays backscattered by tissue toward a convex lens; as consequence of this backscattering, a POSITA would have understood that the backscattered light will encounter the interface provided by the convex board/lens at all locations from a wide range of angles. This pattern of incoming light cannot be focused by a convex lens towards any single location.



APPLE-1052, 141 (annotated)

33. To the extent Masimo contends that only *some* light is directed "towards the center" and away from Aizawa's detectors in a way that discourages combination, such arguments also fail. Indeed, far from *focusing* light to a single central point, a POSITA would have understood that Ohsaki's cover provides a slight refracting effect, such that light rays that may have missed the active detection area are instead directed toward that area as they pass through the interface provided by the lens. APPLE-1051, 52; APPLE-1007, [0015]; APPLE-1052, 87-92, 135-141; APPLE-1034, 60:7-61:6, 70:8-18.

34. Patent Owner and Dr. Madisetti's reliance on drawings provided in paragraphs 119-120 of my Original Declaration filed in IPR2020-01520 for justification of their understanding of Inokawa's lens is similarly misplaced. POR, 15-16; APPLE-1041, 41:7-22, 60:7-61:6. Far from demonstrating the false notion that a convex lens directs all light to the center, these drawings I previously provided are merely

simplified diagrams included to illustrate, as per dependent claim 12, one example scenario (based on just one ray and one corpuscle) where a light permeable cover can "reduce a mean path length of light traveling to the at least four detectors." Ex. 2020, ¶¶119-120. As previously illustrated, there are many other rays that would intersect the interface between the tissue and the lens at different locations and with different angles of incidence, and the effect of the lens on this variety of rays is not nearly as simple as the statements provided by Dr. Madisetti. There is simply no possibility of any lens focusing all incoming rays from a diffuse light source toward a central location.

B. A POSITA would have been motivated to add a second LED to Aizawa

35. As laid out in detail in my Original Declaration, a POSITA would have been motivated to add a second emitter operating at a different wavelength to Aizawa in order to allow for a more reliable pulse measurement that takes into account and corrects for inaccurate readings stemming from body movement. APPLE-1003, ¶¶69-81.

36. Patent Owner, however, suggests that such motivation is flawed because "Aizawa...expressly states that it provides a "device for ***computing*** the ***amount*** of motion load from the pulse rate.'" POR, 38. But Patent Owner fails to explain how Aizawa senses and computes motion load. Indeed, Aizawa is completely silent on this point. Moreover, while Patent Owner contends that Aizawa "account[s] for" motion, Aizawa does not even

say whether it uses the computed motion load to improve the detection signal. Patent Owner further fails to rebut that adding a second LED having a second wavelength, as per Inokawa, will "allow for a more reliable" reading that compensates for body motion. APPLE-1003, ¶72. Like I explained during my deposition, adding a second LED at a different wavelength to Aizawa's single LED design would allow it to obtain a more reliable pulse measurement by allowing the system to "measur[e] pulse rate and motion load during the same time" by operating a separate LED dedicated to sensing motion. Ex. 2007, 401:11-402:4. Moreover, having two separate signals that are respectively dedicated to measuring pulse and body motion, as per Inokawa, will allow Aizawa's system to "take into account and correct for inaccurate readings related to body movement" by subtracting the "signal component corresponding to body movement [] from the pulse signal to help better isolate the desired pulse data." APPLE-1003, ¶72.

37. By using two wavelengths, it is possible to record two independent signal waveforms at the same time from the same site. As explained above, each reflected signal includes some dependence on the physiological parameter, and on the movement of the sensor relative to the measurement site. Because it is possible to choose different wavelengths of light so as to have one signal with strongest dependence on the physiological parameter

and the second signal with the strongest dependence on the movement of the sensor, the signals can be processed in a way to compensate for movement and create a more reliable measurement of the physiological parameter. The use of two or more separate wavelengths to obtain independent measures of the physiological parameter and error sources such as body movement, was well-known at the time of the invention, and it would have been obvious for a POSITA to consider the use of a second wavelength LED to capture these benefits.

38. Inokawa provides a second and independent motivation for adding a second LED having a different wavelength, namely the ability to "improve data transmission accuracy by using the second LED...to transmit checksum information such that 'the accuracy of data can be increased." APPLE-1008, [0111], [0044], [0048]; APPLE-1003, ¶78. The fact that "Inokawa states that it can accomplish transmission with a ***single*** LED" does not take away from the fact that a POSITA would nevertheless have been motivated to look to the two-LED implementation of Inokawa to further improve accuracy. POR, 40; Ex. 2007, 407:7-408:20. Despite Patent Owner's contention that I "acknowledged that POSITA wanting to maintain a wireless data transmission approach [in Aizawa] would not switch to the base station transmission approach of Inokawa," POR, 41, a full reading of transcript reveals that I was simply making it very clear that if "they've

already decided not to use a base station transmission device, then they probably wouldn't switch to one." Ex. 2007, 416:5-15. As for Patent Owner's assertion that Aizawa's goal is "real-time measuring," I note that there is no disclosure in Aizawa indicating that such measured data must also be transmitted externally in real-time. POR, 40. Moreover, a POSITA would have been capable of balancing potential benefits associated with different data transmission approaches, for instance improved transmission accuracy on one hand and quicker transmission on the other.

39. Patent Owner additionally argues that "Petitioner fails to address other complications that would result from adding an extra LED to a physiological sensor," such as the potential for "thermal interference." POR, 41. But as I again explained during my deposition and reiterate here, such minor issues are "part of what I understand someone of ordinary skill in the art would bring...to the problem and would know how to make the changes needed." Ex. 2007, 384:8-388:12.

C. A POSITA would have been motivated to modify Aizawa in view of Ohsaki to include a convex protrusion

40. As explained in my Original Declaration, "Ohsaki teaches that adding a convex surface...can help prevent the device from slipping on the tissue of the wearer compared to using a flat cover without such protrusion" and that "a POSITA seeking to achieve improved adhesion between the detector and the skin, as expressly recognized in Aizawa, would have been motivated and readily able to modify

Aizawa's acrylic plate to have a convex shape as in Ohsaki." APPLE-1003, ¶¶126-128 (citing to APPLE-1014, [0025]; APPLE-1006, [0026], [0030]).

41. Patent Owner, rather than attempting to directly rebut this rationale, focuses on arguments that are factually flawed and legally irrelevant. Specifically, Patent Owner contends that Ohsaki's "convex surface must have ***longitudinal directionality***," and that "Ohsaki indicates that its convex surface ***only prevents slipping on the backhand side*** (i.e., watch-side) of the user's wrist." POR, 44. Patent Owner further asserts that the shape of Ohsaki's board must be limited to a long, narrow rectangular shape while ignoring that the specification includes no specific limitation on the shape of the board.

42. Notably absent from the POR is how Ohsaki ***actually*** describes the benefits associated with its convex surface. For example, Ohsaki contrasts a "convex detecting surface" from a "flat detecting surface," and explains that "if the translucent board 8 has a flat surface, the detected pulse wave is adversely affected by the movement of the user's wrist," but that if "the translucent board 8 has a convex surface…variation of the amount of the reflected light…that reaches the light receiving element 7 is suppressed." APPLE-1014, ¶[0025]. But a POSITA would have understood from such teachings of Ohsaki that the advantages of a light permeable protruding convex cover could apply regardless of any alleged longitudinal directionality of Ohsaki's cover and regardless of where on the body such a convex cover was placed. *See* APPLE-1014, ¶¶[0015], [0017], [0025], FIGS.

1, 2, 4A, 4B. This is because Ohsaki was relied upon not for its exact cover configuration but rather for the rather obvious concept that a convex surface protruding into a user's skin will prevent slippage, regardless of any directionality that may or may not exist with respect to such convex surface and regardless of where on the human body it is located. *See* Ex. 2012, 91, 87; APPLE-1014, ¶¶[0015], [0017], [0025], FIGS. 1, 2, 4A, 4B. In fact, Ohsaki says nothing about the exact dimensions or even anything specific about the required shape of the board, except that it provides a convex protrusion. A POSITA would seek to combine the board of Ohsaki with Aizawa by making reasonable modifications as needed to ensure that the board of Ohsaki was compatible with the other features present in Aizawa. A POSITA would find it obvious to consider selecting a shape for the board that is consistent with the shape of the system presented in Aizawa, and would expect that the benefits associated with the convex board of Ohsaki would be present in the combination. And adding a convex surface to Aizawa's flat plate will serve to ***improve*** its tendency to not slip off, not take away from it, since it is well understood that physically extending into the tissue and displacing the tissue with a protrusion provides an additional adhesive effect. Aizawa provides a plate that improves adhesion with the surface. Ohsaki further teaches that the convex protrusion provides "intimate contact" with the tissue, which helps prevent the detecting element from slipping off. These benefits are clearly related and complimentary, and a POSITA would appreciate that modifying the plate of Aizawa to include a convex

protrusion as in Ohsaki would provide improved performance, and that these benefits can be obtained by making obvious modifications to the board in Ohsaki to accommodate the shape of Aizawa.

43. Indeed, Ohsaki's specification and claim language reinforce that Ohsaki's description would not have been understood as limited to one side of the wrist. For example, Ohsaki explains that "the detecting element 2…may be worn on the back side of the user's forearm" as one form of modification. *See* APPLE-1014, [0030], [0028] (providing a section titled "[m]odifications"). The gap between the ulna and radius bones at the forearm is even greater than the gap between bones at the wrist, which is already wide enough to easily accommodate a range of sensor sizes and shapes, including circular shapes. In addition, Ohsaki's claim 1 states that "the detecting element is constructed to be worn on a back side of a user's wrist ***or a user's forearm***." *See also* APPLE-1014, claims 1-2. As another example, Ohsaki's independent claim 5 and dependent claim 6 state that "the detecting element is constructed to be worn on a user's wrist or a user's forearm," ***without even mentioning a backside*** of the wrist or forearm. *See also* APPLE-1014, Claims 6-8. A POSITA would have understood that Ohsaki's benefits provide improvements when the sensor is placed on either side of the user's wrist or forearm. APPLE-1014, [0025], FIGS. 4A, 4B. And while Masimo appears to contend that Ohsaki teaches that a convex cover at the front (palm) side of the wrist somehow *increases* the tendency to slip, this is an argument that is nowhere supported by Ohsaki. For

instance, paragraph 23 and FIGS. 3A-3B of Ohsaki that Masimo points to as allegedly providing support for this incorrect argument mentions nothing about the flat/convex nature of the cover and is instead merely demonstrating that pulse detection is generally less reliable when the user is in motion (and thus would benefit from changes such as adding a convex cover). APPLE-1014, [0024], FIGS. 4A, 4B

44. POR presents several arguments with respect to Ground 1 that are premised on Ohsaki ***requiring*** the detecting element to be worn on a back side of a user's wrist or a user's forearm. Because Ohsaki requires no such location for the translucent board 8, these arguments fail.

III. Ground 2 Establishes Obviousness

45. As I further clarify below in response to Patent Owner's arguments, claims 1-6, 8-16, 18, and 19 are rendered obvious by the combination of Mendelson-1988 and Inokawa (Ground 2).

A. Inokawa's lens similarly enhances the light-gathering ability of Mendelson-1988

46. Similar to their rebuttal of the Aizawa-based grounds, Patent Owner contends that (1) "Inokawa's convex lens focused light on a ***centrally located*** detector" and (2) as a result, incorporating such a lens to Mendelson-1988 would cause the "lens to direct light ***away*** from the detectors" based on Mendelson-1988's use of centrally-located LEDs. POR, 48-50. For reasons discussed at length above, basic optical principles and a proper understanding of reflectance-type sensors as in Aizawa, Inokawa, and Mendelson-1988 would have led a POSITA to understand that adding

an Inokawa-like lens to Mendelson-1988 would result in additional benefits such as enhanced light-gathering ability and improved signal-to-noise ratio. Again, as noted above, Patent Owner's fundamentally flawed characterization of the lens of Inokawa as "focusing [light] on a single central detector" runs contrary to basic principles of optics and how lenses work.

B. Mendelson-1988 in view of Inokawa includes the claimed cover

47. As I previously explained, the Mendelson-1988-Inokawa combination provides protruded epoxy cover that acts as a lens and also covers the detectors. APPLE-1003, ¶¶136-145. Patent Owner argues, however, that "the '191 Patent distinguishes a resin on a surface from a cover" and, as a result, the modified Mendelson-1988 device lacks a cover. POR, 51-52.

48. A POSITA would understand the plain meaning of cover to be merely "something that protects, shelters, or guards." APPLE-1050. Both instances of the "light permeable cover" as I previously identified are clearly covers that serve to protect. There is nothing in the specification of the '191 Patent itself that suggests that some special meaning is attributed to the term "cover" as used in the patent.

49. Patent Owner mischaracterizes my deposition testimony to make it sound like I agreed that "sealing resin" is somehow different from a cover. POR, 51-52 (citing to Ex. 2009, 395:22-396:17). My actual testimony, if one reads it fully, clearly shows that no such statement was made. *See* Ex. 2009, 396:9-17 ("Q. So [using a

sealing resin] would be one way to protect the components without using a cover, correct? A. There are many ways to protect the elements other than using a cover. The purpose of the cover in this combination is also to improve adhesion and to improve light gathering for the operation of the system."). Rather, I was merely clarifying that using a sealing resin is "a pretty common way to protect electronic components." *Id.*, 395:22-396:8.

50. Moreover, while Patent Owner points to a cherry-picked passage from the '191 Patent to suggest that it distinguishes "cover" from "resin epoxies," POR, 51-52 (citing APPLE-1001, 36:50-59 ("[The cover] can protect...***more effectively*** than currently-available ***resin epoxies***."), Patent Owner failed to reproduce the rest of the sentence, which reads: "...more effectively than currently-available resin epoxies, ***which are sometimes applied to solder joints between conductors and detectors***." APPLE-1001, 36:50-59. That is, the epoxy resin to which the '191 Patent compares its cover is not the epoxy cover as contemplated in the Mendelson-1988 combination but rather epoxy that is applied to solder joints.

51. As for Patent Owner's suggestion that the claimed "cover" must be "distinct" from all other components, which I disagree with, I previously explained how a POSITA, looking at conventional epoxy processing techniques such as those found in Nishikawa, would have added an additional epoxy lens layer separately on top of the epoxy encapsulation layer underneath, thereby providing a separate and differentiated mass of material to serve as the cover. APPLE-1003, ¶142-144 (citing

to APPLE-1023, [0034]-[0038], FIGS. 5-6).

C. Mendelson-1988 in view of Inokawa renders obvious a "plurality of detectors in a circular portion of the housing" and a "lens configured to be located between tissue of the user and the plurality of detectors"

52. Regarding this feature, I previously explained that there was nothing new or inventive about changing a rectangular housing for a circular one and that a POSITA, among other things because microelectronic packaging as used in Mendelson-1988 comes in various shapes and sizes. APPLE-1003, ¶¶133-135. Patent Owner rebuts this simple change in design by arguing that "[a] POSITA would have no particular motivation to change the shape unless a POSITA perceived some benefit in doing so." POR, 52-54. But there is nothing in the '191 Patent or in the POR that explains how the particular housing shape solves some problem or presents some unexpected result. Rather, a POSITA would have simply recognized that housing shape is a non-inventive feature and that it would have been quite routine to use a differently shaped housing. *See* APPLE-1003, ¶¶133-135. Indeed, given that many other references, such as Mendelson-799 (APPLE-1025), explicitly show the use of circular walls/housings, a POSITA would have found it to be simply a matter of design choice to use a differently shaped walls/housings.

D. Nishikawa is a supporting reference

53. Despite Patent Owner's assertions, I consistently referred to Nishikawa in my Original Declaration merely as an example among various prior art references of the period that "demonstrate exactly how [a convex] lens shape may be incorporated into

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APPLE INC.
Petitioner,

v.

MASIMO CORPORATION,
Patent Owner.

Case IPR2021-00209
U.S. Patent 10,376,191

DECLARATION OF VIJAY K. MADISETTI, PH.D.

Masimo Ex. 2004
Apple v. Masimo
IPR2021-00209

incorporate a convex lens as in Inokawa into Aizawa's acrylic plate to thereby increase light collection efficiency, in turn leading to more reliable pulse wave detection." Ex. 1003 ¶88. Dr. Kenny repeats that "Aizawa is modified to include a lens (right) as per Inokawa in order to 'increase the light-gathering ability.'" Ex. 1003 ¶89 (quoting from Inokawa, Ex. 1008 ¶15).

B. Ground 1A Does Not Establish Obviousness

1. A POSITA Would Not Have Been Motivated To Combine Inokawa's Convex Lens With Aizawa's Sensor

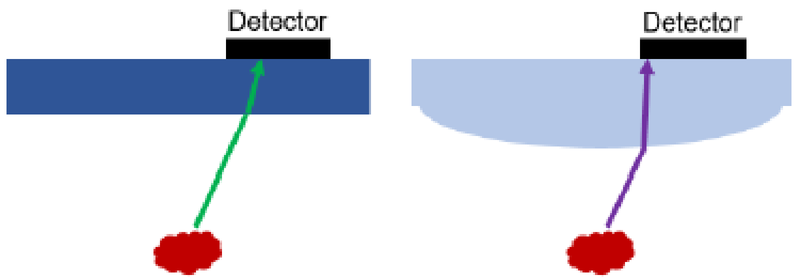
a) Dr. Kenny and Petitioner Admit That Inokawa's Convex Lens Directs Light To The Center Of The Sensor

48. Both Dr. Kenny and Petitioner agree that Inokawa's convex lens condenses light towards a centrally located detector—not periphery-located detectors like those used in Aizawa, as demonstrated by their admissions in this proceeding and their submissions in an IPR (IPR2020-01520 (Ex. 2019; Ex. 2020)) of related patent U.S. Pat. No. 10,258,265 (Ex. 2025). U.S. Pat. No. 10,258,265 and the '191 Patent share a common specification. U.S. Pat. No. 10,258,265 is at least a continuation of U.S. Patent App. No. 14/981290. The '191 Patent is at least a continuation of U.S. Patent App. No. 16/261326, which at least a continuation of U.S. Patent App. No. 16/212537, which is at least a continuation of U.S. Patent App. No. 14/981290.

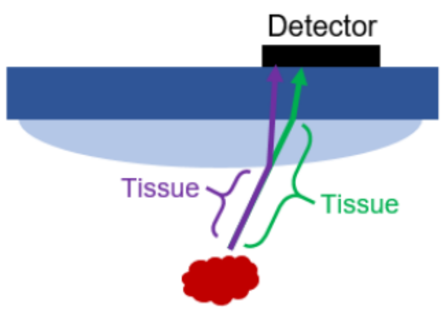
49. Petitioner included the illustrations below in its Petition in this proceeding when discussing claim 6 of the '191 Patent, as well as its Petition in

IPR2020-01520 when discussing claim 12 of U.S. Pat. No. 10,258,265. Pet. 33; Ex. 2019 at 45. Petitioner explained that "the lens of Inokawa, which is used to modify Aizawa ... serves a condensing function and thus, as with any other lens, refracts light passing through it." Pet. 33; Ex. 2019 at 44. Petitioner explained the drawing below as comparing "the length of non-refracted light (*i.e.*, without a lens, left) bouncing off an artery with that of refracted light (*i.e.*, with a lens, right)." Pet. 33; Ex. 2019 at 44-45. Refraction is a phenomenon related to the velocity of light in different materials because the velocity of light depends on the material through which it is traveling. Thus, the change in velocity as light moves from one material to another material may cause the light to deviate from its original direction, which is called "refraction." I note that the illustration below shows refraction for both the flat and convex surfaces because in both instances the illustrated light ray changes direction. Moreover, I note that, as illustrated by Petitioner, the change of direction for the light ray hitting the convex surface is relatively more towards the center of the cover than for the flat cover. Petitioner states that the result of the greater refraction of light with the convex cover with a protruding surface is that "the mean path length of light traveling to the at least four detectors is reduced—that is, the purple line is shorter than the green line." Pet. 33; *see also* Ex. 2019 at 45. Petitioner also includes a drawing superimposing the two drawings below to "clearly show[] the shortened path traveled by refracted

light in the presence of a protrusion/lens, both within the tissue as well as for total path length." Pet. 34; Ex. 2019 at 45.



Petitioner's illustration of redirection of the mean path length
of light traveling to the detectors when passing
through a flat (left) and convex (right) cover (Pet. 33; *see also* Ex. 2019 at 45)



Petitioner's illustration superimposing the above refractions
when illustrating how a convex surface a protruding surface changes the
mean path length of incoming light (Pet. 34; *see also* Ex. 2019 at 45, 91)

50. Dr. Kenny also included and explained the two figures above in his declarations in this proceeding and IPR2020-01520 (Ex. 2020) as a way to illustrate the mean path length of light. Ex. 1003 ¶¶102-103; Ex. 2020 at 69-70. Dr. Kenny explained that, when using a protruding surface such as Inokawa's convex lens, "the incoming light is 'condensed' toward the center." Ex. 1003 ¶102; Ex. 2020 at 69-70. Dr. Kenny goes on to explain: "Laying these two

drawings on top of each other…the shortened path length within the tissue for the purple (refracted) line can be clearly seen compared to the path length within the tissue of the green (non-refracted) line." Ex. 1003 ¶103; Ex. 2020 at 70-71.

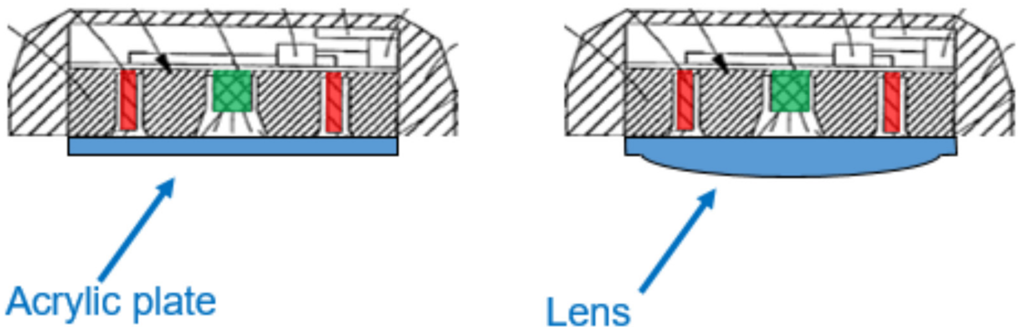
51. The understanding expressed by Petitioner and Dr. Kenny about condensing light is consistent with Inokawa's disclosure, which uses a convex surface as a way to increase the light gathering capability for a centrally located detector. Ex. 1008 ¶[0058], Fig. 2. As shown in Figure 2 (below), Inokawa illustrates how a protruding surface placed between the sensor and the skin condenses incoming light towards the central detector 25. Ex. 1008 ¶[0058], Fig. 2. This is helpful for Inokawa's particular sensor configuration because the emitters are located on the edges of the sensor while the detector is located in the center of the sensor. Thus, for Inokawa's particular linear arrangement of emitter-sensor-emitter, the protruding shape is reported to increase the light gathering capabilities of the centrally located detector when collecting the light emitted by the periphery-located LEDs and reflected by the measurement site. Ex. 1008 ¶[0058], Fig. 2. Inokawa illustrates this by using arrows that illustrate the general path of light from emitters, to the measurement site, and then back towards the central detector.

central location as a result of passing through the protruding surface. Ex. 1001 Fig. 14B.

55. Thus, as discussed, Petitioner, Dr. Kenny, and the '191 Patent all support that a POSITA would have understood that the protruding surface illustrated by Inokawa would direct incoming light towards the center of the sensor. I also agree that a POSITA reading Inokawa would have understood that the protruding surface illustrated by Inokawa would direct incoming light towards the center of the sensor.

b) A POSITA Would Not Have Been Motivated To Direct Light Away From Aizawa's Detectors And Would Have No Reasonable Expectation Of Success When Doing So

56. Although Petitioner and Dr. Kenny both agree that a POSITA would have understood that a protruding surface would converge incoming light toward the center, I understand that Petitioner asserts that a POSITA would place Inokawa's convex lens on the sensor of Aizawa, which has the opposite configuration of components as compared to Inokawa, with peripheral detectors and a central emitter. Petitioner illustrates the result of this change in Aizawa as a device with the emitter (green) in the center and the detectors (red) on the periphery.



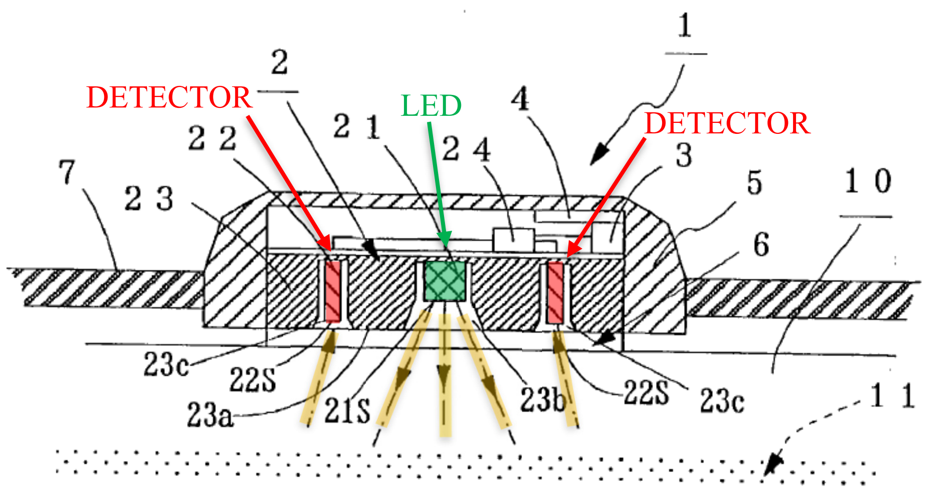
Petitioner's and Dr. Kenny's illustrations (Pet. 27; Ex. 1003 ¶89)
Aizawa's flat surface (left) versus Ground 1A's Proposed Combination (right)
The detectors are red and the emitter is green.

57. Dr. Kenny illustrates this same combination in his declaration. Ex. 1003 ¶89. Dr. Kenny states that "by positioning a lens above the optical components of Aizawa, as shown below, the modified cover will allow more light to be gathered and refracted toward the light receiving cavities of Aizawa, thereby further increasing the light-gathering ability of Aizawa beyond what is achieved through the tapered cavities." Ex. 1003 ¶89. As shown in Inokawa, as well as Dr. Kenny's other figures in his declaration and the '191 Patent, however, a POSITA would not have believed that the illustrated protruding surface would have allowed "more light to be gathered and refracted toward" Aizawa's peripheral detectors. Instead, as discussed above, a POSITA reading Inokawa would have expected more light would be gathered and refracted towards the center of the sensor, which is where Aizawa positions its single emitter.

58. Like Dr. Kenny, Petitioner asserts that a POSITA would have been motivated to "further Aizawa's objective of enhancing its light-collection efficiency." Pet. 27. But, again, a POSITA would not have expected Inokawa's protruding surface to accomplish this goal because, as discussed, a POSITA would have understood that a protruding surface directs light away from the periphery-located detectors. Ex. 1008 ¶[0058], Fig. 2. Thus, in view of Inokawa's teachings of increased light gathering to its central detector, a POSITA would have believed that a protruding surface would have undesirably decreased light-collection efficiency at Aizawa's peripheral detectors and reduced the measured optical signal. Ex. 1008 ¶[0058], Fig. 2.

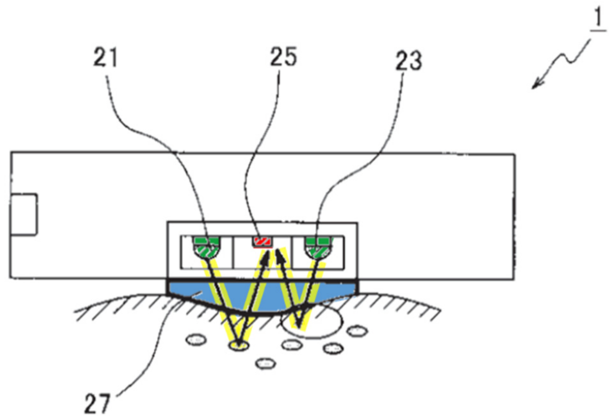
59. As illustrated in Aizawa, light is emitted from a central emitter (e.g., a light emitting diode or "LED") and reaches detectors (e.g., photodetectors) that are disposed around the emitter. Ex. 1006 ¶[0009]. The light emitted from the center-located emitter reflects from the artery of the wrist of the user and travels to the periphery located detectors. Ex. 1006 ¶¶[0009], [0027], [0036]. Thus, as illustrated in Aizawa Figure 1B, the light reaching Aizawa's detectors must travel in the opposite direction compared to the light in Inokawa. Ex. 1006 Fig. 1B. Aizawa states that its detectors "are disposed around the light emitting diode 21 on a circle concentric to the light emitting diode 21 in this embodiment." Ex. 1006 ¶[0027]. Aizawa contrasts its circular arrangement of detectors around an emitter

with the type of linear arrangement illustrated in Inokawa, explaining the photodetectors "should not be disposed linearly." Ex. 1006 ¶[0027]; *see also* ¶¶[0009], [0036]. Aizawa illustrates the light path as leaving a single centrally located emitter, passing through the body, and reflecting back to periphery-located detectors:



Aizawa Fig. 1B (cross-sectional view, color added)

60. As shown below, Inokawa illustrates the opposite emitter/detector arrangement and the opposite required light path for detection: light leaves periphery-located emitters, passes through the body, reflects back, and is focused on a single centrally located detector. Ex. 1008 ¶[0058], Fig. 2.



Inokawa's Features

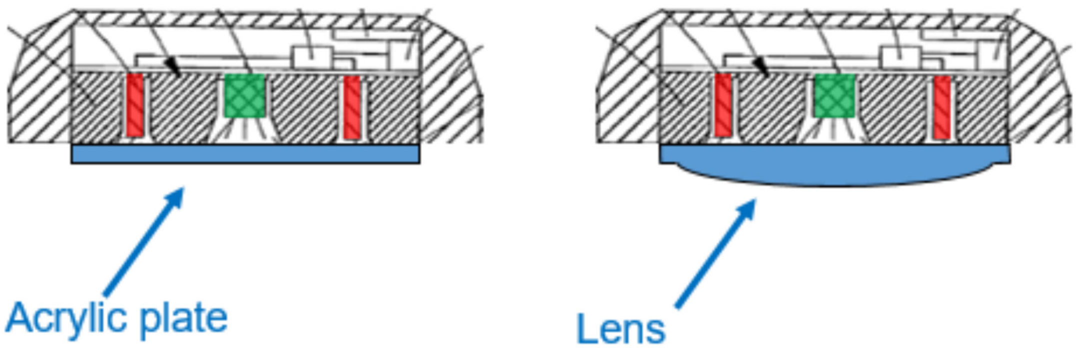
- **Green**: peripheral emitters (21, 23)
- **Red**: central detector (25)
- **Blue**: convex lens (27)
- Arrows showing direction of light in original, highlighted in yellow

Inokawa Fig. 2 (color added)

61. In my opinion, a POSITA would have linked the benefit of increased light gathering described in Inokawa to the arrangement of peripheral emitters and center-located detector, and thus would have believed that the benefit of increased light gathering resulting from Inokawa's protruding surface made sense in view of Inokawa's configuration using a centrally located detector. Ex. 1008 ¶[0058], Fig. 2. In contrast, a POSITA would have understood that Inokawa's protruding surface would not be suitable for achieving a goal of improved light gathering in Aizawa's sensor, because Aizawa uses a circular arrangement of peripheral detectors arranged around a central emitter and contrasts its approach to a linear detector/emitter arrangement. Ex. 1006 ¶¶[0009], [0027], [0036], Fig. 1B; *see also* Figs. 1A, 2, 4, 5.

62. As shown in the structure that Dr. Kenny and Petitioner assert would have resulted from the proposed combination of Inokawa and Aizawa (reproduced below), the result of the proposed combination places the emitter at the very center

of the protruding surface, which is the position at which the returning light would be concentrated.

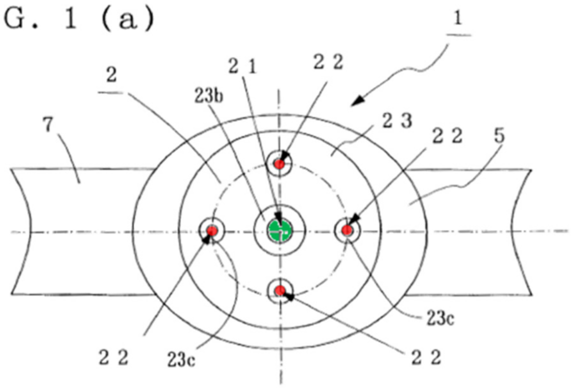


Petitioner's and Dr. Kenny's illustrations (Pet. 27; Ex. 1003 ¶89)
Aizawa's flat surface (left) versus Ground 1A's Proposed Combination (right)

63. In my opinion, a POSITA would have found this combination of a protruding surface with Aizawa's sensor particularly problematic because—consistent with Aizawa—the combination includes small detectors with small openings surrounded by a large amount of opaque material. Pet. 27; Ex. 1003 ¶89; Ex. 1006 Fig. 1B; *see also* Figs. 1A, 2, 4A-4B, 5. Aizawa's top-down view shown in Figure 1A confirms the detectors' small size. Ex. 1006 Fig. 1A; *see also* Figs. 2, 4A-4B. Aizawa Figure 1A is reproduced below with the detectors highlighted in red and the emitters highlighted in green. Aizawa explains that the openings of the detector cavities (23c in the figure below) are larger than the size of the photodetector itself, and intended to "expand…the light receiving areas of the

photodetectors… [and] are tapered such that their widths increase toward the contact face." Ex. 1006 ¶[0024].

FIG. 1 (a)



Aizawa's Features

- **Green**: central emitter (21)
- **Red**: peripheral detector (22)

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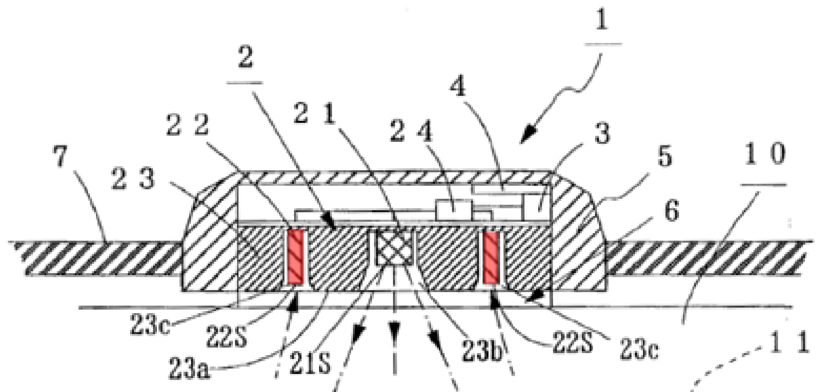
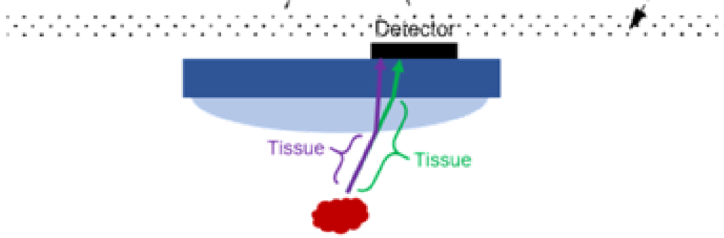
64. When discussing the change in light path for light interacting with a convex surface, Dr. Kenny's declaration does not use either Aizawa's structure or what Dr. Kenny asserts would have been the result of combining Aizawa and Inokawa. Instead of using Aizawa's actual structure (below, top), Dr. Kenny presents a separate figure (below, bottom) that drastically increases the size of a detector compared to Aizawa and eliminates the surrounding barriers.



Aizawa's figure illustrating detectors (22, red)
(Ex. 1006 Fig. 1B)



Dr. Kenny's depiction drastically increasing size of Aizawa's detector (black)
(Ex. 1003 ¶103)

65. Applying Dr. Kenny's illustration of the redirected light path (illustrated by the purple line in the second figure above) to Aizawa's actual detectors (highlighted in red in the first of the two figures above) confirms the redirected light would not even reach the detectors because it would miss both Aizawa's small detectors and even the slightly larger cavities due to passing through the convex surface. It appears that Dr. Kenny increased the size of Aizawa's detector approximately five-fold to so that the redirected light reached the detector, and also eliminated the opaque barrier of Aizawa's holder 23 entirely. There is no analysis or explanation of these changes in Dr. Kenny's declaration, or any acknowledgement that the redirection of light towards a more central location would have caused the redirected light to miss Aizawa's detectors entirely. *See*

Ex. 1003 ¶¶102-103 (No indication that size of Aizawa's detectors had to be changed in order to still detect light redirected by convex surface).

c) <u>Dr. Kenny's Testimony Further Undermines Obviousness</u>

66. Dr. Kenny's declaration includes figures that he describes as illustrating the phenomenon of how "the incoming light is 'condensed' toward the center," after interacting with a protruding surface. Ex. 1003 ¶¶102, 156; *see also* Ex. 2020 at 69-70. The term "condensing" in the context of light passing through a surface describes the general understanding of a POSITA that light is directed towards a more central location when passing through a protruding surface, and thus results in a relative increase of light at the center and decrease of light at the peripheral edge of underlying structure. I further note that the figures at paragraphs 102-103 in Dr. Kenny's declaration are used with respect to a limitation involving the "mean path length of light traveling to the at least four detectors." Ex. 1003 ¶¶103, 157; *see also* Ex. 2020 at 69-71, 115-117. In particular, the limitation Dr. Kenny analyzed is: "The noninvasive optical physiological sensor of claim 4, wherein the lens is configured to reduce a mean path length of light traveling to the plurality of detectors." Further, in my opinion, as discussed above, a POSITA would have believed that the protruding surface in Inokawa would have redirected more light overall to the center of the sensor, resulting in relatively more

data processing and not sensor design. Training in data processing would not have prepared a POSITA for the type of design process identified by Dr. Kenny as needed to develop a working optical physiological sensor.

74. A POSITA would have understood that Inokawa's convex lens benefits Inokawa's sensor design with its center-located detector. Ex. 1008 ¶58, Fig. 2. In my opinion, a POSITA would have credited the teaching of Inokawa itself, which shows that a protruding surface directs incoming light towards the center. Ex. 1008 ¶58, Fig. 2. In contrast, I do not believe a POSITA would have been motivated to go through Dr. Kenny's extensive trial and error process to try and figure out whether Inokawa's protruding surface would have analogous benefits in a device with peripheral detectors and a central emitter. Instead, a POSITA would have taken Inokawa's teaching at face value, consistent with the general understanding of how light interacts with a protruding surface.

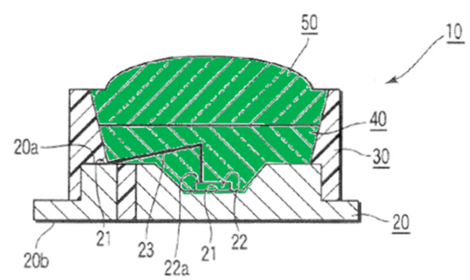
75. Thus, accounting for the possibility that a POSITA with no experience in optical physiological sensor design would nonetheless understand the wide ranging considerations identified by Dr. Kenny at his deposition in related IPRs, it is still my opinion that Inokawa does not establish a valid motivation to combine Inokawa with Aizawa, much less a reasonable expectation of success. When addressing a reasonable expectation of success, Dr. Kenny focuses his discussion on the manufacturing of a device, and not whether the device would be able to

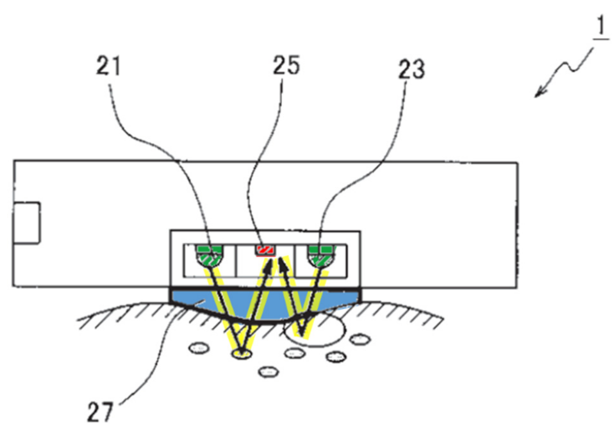
successfully act as a physiological monitor or sensor. See, e.g., Ex. 1003 ¶¶90-91. Whether or not "the shape of the cover can be readily modified" (Ex. 1003 ¶90), Dr. Kenny never explains why a POSITA would have expected Petitioner's proposed combination to result in a successful optical physiological sensor. The lack of analysis is particularly important because a POSITA would have expected a protruding surface to decrease the optical signal at the peripheral detectors. The possibility that POSITA could manufacture a device is not evidence a POSITA would have reasonably expected the resulting device to successfully work as an optical physiological measurement device. Decreasing the amount of light reaching the detectors will decrease the signal, increase the relative amount of noise, and could thus result in a signal unusable for actually monitoring a physiological parameter.

d) Petitioner's Obviousness Challenge Also Relies On References Not Identified As Part Of Ground 1A Without A Motivation To Combine Or Expectation Of Success

76. I further note that the Petition, and Dr. Kenny's analysis, apparently relies on references that neither the Petitioner nor Dr. Kenny identifies as part of Ground 1A. The Petition states that Ground 1A includes only two references: Aizawa and Inokawa. Pet. 2. But Dr. Kenny's analysis also relies on another cited reference: Nishikawa. Ex. 1003 ¶¶86-91.

illustrates that LEDs with curved surfaces similar to Nishikawa's LEDs are a fraction of the size of the sensor or cover. Ex. 1008 Fig. 2 (21, 23). Likewise, Aizawa similarly illustrates that the LED is a much smaller part of the overall sensor. Ex. 1006 Fig. 1; *see also* Figs. 4, 5. Thus, given the differences between Nishikawa on the one hand and Inokawa and Aizawa on the other hand, a POSITA would not have been motivated to apply Nishikawa's lens design in a physiological sensor and would have had no expectation of success in doing so.





Comparison of Nishikawa's LED package (left) & Inokawa's sensor Fig. 2 (right) showing scale difference (LED package highlighted in green in both)

2. A POSITA Would Not Have Added A Second Emitter (LED) To Aizawa

79. Even if a POSITA were motivated to combine Aizawa and Inokawa, the combination of Aizawa and Inokawa still would not result in the claimed invention because, in my opinion, it does not disclose all of the claim limitations. Every claim of the '191 Patent requires (1) a plurality of emitters and (2) at least four detectors. Ex. 1001 Claims 1 and 9. Neither Aizawa nor Inokawa includes

both a plurality of emitters and at least four detectors. *See, e.g.*, Ex. 1006 Fig. 1 (single center-located emitter with multiple peripheral detectors); Ex. 1008 Fig. 2 (two peripheral emitters with a single center-located detector). Neither Aizawa nor Inokawa disclose or suggest the use of both multiple detectors and multiple emitters in the same sensor.

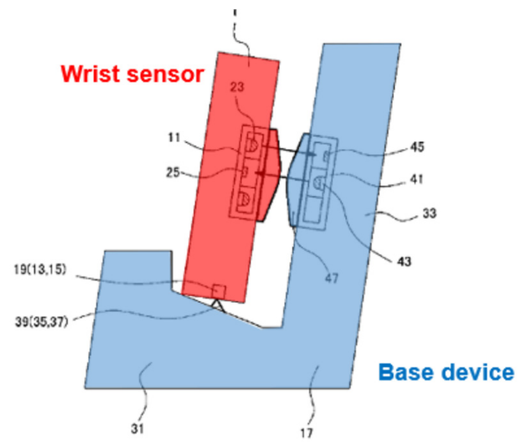
80. Aizawa has no disclosure of a sensor with multiple detectors and multiple emitters. To the extent Dr. Kenny suggests Aizawa teaches the use of multiple detectors and multiple emitters in a single sensor, I disagree. In one of Aizawa's embodiments, multiple detectors surround a single centrally located LED. Ex. 1006 ¶[0033], Figs. 1A-1B, 2, 4A-4B, 5. In this embodiment, Aizawa teaches the number of photodetectors "disposed around the light emitting diode" can be increased or decreased. Ex. 1006 ¶[0032]. In Aizawa's other embodiment, which is not illustrated, multiple LEDs surround a single centrally located detector. *See* Ex. 1006 ¶[0033] ("The same effect can be obtained when the number of photodetectors 22 is 1 and a plurality of light emitting diodes 21 are disposed around the photodetector 22."). Inokawa likewise discloses an arrangement where two LEDs are used on either side of a single detector. Ex. 1008 ¶[0058], Fig. 2. Neither reference discloses a sensor with multiple emitters used with multiple detectors.

Inokawa, like Aizawa, flank a single center-located detector. *See* Ex. 1008 ¶[0058] ("[T]he pulse sensor 1 is comprised of a pair of light-emitting elements ... [and] a single photodiode."). There is no multi-detector/multi-emitter embodiment disclosed in either Aizawa or Inokawa, and no reason why a POSITA would have been motivated by these references to change both references to use a multi-detector/multi-emitter arrangement. Dr. Kenny asserts that "it was common practice in the pulse oximeter field to centrally locate multiple emitters of different wavelengths" (Ex. 1003 ¶80); this is irrelevant to Aizawa because Aizawa is not an oxygen saturation sensor, it is a pulse wave sensor (Ex. 1006 ¶[0002]).

84. Dr. Kenny points to two reasons why Inokawa would have motivated a POSITA to add a second LED to Aizawa. First, Dr. Kenny asserts that a POSITA would have added a second LED based on the "added ability to measure body movement." Ex. 1003 ¶72; *see also* ¶73. But Aizawa already includes this functionality, and explains that it provides a "device for computing the amount of motion load from the pulse rate." Ex. 1006 ¶[0015]. There is no need for a design change when Aizawa already includes the relevant functionality.

85. Second, Dr. Kenny asserts that adding a second LED would enable Aizawa to transmit data to a base device with a configuration like that in Inokawa. Ex. 1003 ¶76. Dr. Kenny asserts that "Aizawa contemplates uploading data from its wrist sensor to an external base device" and would have incorporated Inokawa's

base device "that both charges and receives data from the pulse sensor." Ex. 1003 ¶76.



Dr. Kenny's Illustration of Inokawa's Base Device (Ex. 1003 ¶76)

86. But Aizawa already includes a transmitter in its structure, so Aizawa does not need to incorporate Inokawa's base-device data transmission approach. Ex. 1006 ¶¶[0023], [0028], [0035]. Moreover, Aizawa's goal is "real-time measuring" (Ex. 1006 ¶[0004]) with the transmitter "transmitting the measured pulse rate data to a display," (Ex. 1006 ¶[0015]). As Dr. Kenny acknowledged, Aizawa's sensor is designed for monitoring heart rate at the time of exercise. Ex. 2020 at 59. Inokawa's base device, however, only transmits pulse rate data "when the pulse sensor ... is mounted onto the base device." *See, e.g.*, Ex. 1008 Abstract. Inokawa's system thus requires the user to remove the monitoring device, thus stopping the monitoring, and attach it to a base solution before the sensor can transmit data. Ex. 1008 Figs. 3, 8. Transforming Aizawa into a base-device-transmitter eliminates the ability to take and display real-time measurements, one

of Aizawa's stated goals, while increasing power consumption and cost by adding an additional LED. Ex. 1008 ¶[0033].

87. Inokawa would not have motivated a POSITA to make such a change to Aizawa. Dr. Kenny admits that Inokawa can accomplish transmission with a single LED. Ex. 1003 ¶78; *see also* Ex. 1008 ¶[0062]. Inokawa adds a second LED to provide an improvement to help address two situations, neither of which applies to Aizawa. One situation is in a mechanically connected system, where there may be a "risk of contact failure due to damage or deterioration." Ex. 1008 ¶[0004]. That potential improvement is irrelevant since Aizawa's wrist-worn device (Ex. 1006 Fig. 2) uses a transmitter—not a mechanically connected cable. The second possible situation is not having to use a "dedicated wireless communication circuit…." Ex. 1008 ¶[0004]. Aizawa, however, already has a transmitter that provides real-time heart measurements to a display. Dr. Kenny's asserted motivations do not explain why a POSITA would (1) redesign a sensor by adding a second LED, (2) find it desirable to require the use of a separate base station for data transfer and charging, and (3) require the user to remove the device to transmit data when the ultimate result is to remove a transmitter circuit that was already present in Aizawa.

88. Among other things, Dr. Kenny does not address other complications that would result from adding an extra LED to a physiological sensor. For

B. Ground 2 Does Not Establish Obviousness

1. Ground 2 Does Not Demonstrate A Motivation To Combine Mendelson-1988 And Inokawa, And Does Not Establish A Reasonable Expectation Of Success

103. The proposed combination of Mendelson-1988 and Inokawa suffers from the same problems as the proposed combination of Aizawa and Inokawa. In the proposed Mendelson-1988-Inokawa combination, as in the proposed Aizawa-Inokawa combination, the detectors are on the periphery of the device. Ex. 1015 at 2, Figs. 2A-2B. As explained above, Inokawa's convex lens focuses light on a centrally located detector. *See* ¶¶42-61 and 66-75 of this declaration, above; *see also* Ex. 2020 at 115-117 (Dr. Kenny explaining that light passing through a convex surface is condensed towards the center relative to a flat surface). A POSITA would not have been motivated to incorporate a protruding surface to direct light away from the detectors for the same reasons discussed above. *See* ¶¶42-61 and 66-75 of this declaration, above.

104. As shown in Dr. Kenny's illustration below, the proposed combination of Mendelson-1988 and Inokawa positions detectors (Mendelson-1988's photodiodes) on the periphery of the sensor: